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Fentanyl and Propofol Used at The Conclusion of Anesthesia in Pediatrics Patients to Reduce Emerging Anxiety Following Sevoflurane Anesthesia: A Comparative Study in Libyan Patients

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Abstract

Background: The optimal drug for reducing emergence agitation (EA) after sevoflurane anesthesia remains unclear, with both propofol and fentanyl as potential options.

Aim: This study aimed to compare the effects of fentanyl and propofol on the incidence and severity of postoperative agitation and excitement following sevoflurane anesthesia.

Methods: Sixty-six children who underwent sevoflurane anesthesia were prospectively assigned to three groups. Group P received propofol 1 mg/kg, Group F received fentanyl 1 µg/kg, and Group S received saline. EA was assessed using the Pediatric Anesthesia Emergence Delirium (PAED) scale, alongside recovery time and the occurrence of nausea and vomiting.

Results: Group P and Group F had mean PAED scores of 5.05 and 5.2, respectively (p=0.715), significantly lower than Group S (14, p<0.001). Group F had a significantly higher frequency of nausea and vomiting compared to Group P (p<0.001), while differences between Groups P and S were not clinically significant. Group P had a shorter stay in the post-anesthesia care unit (PACU) than Group F (p=0.06), though this difference was not clinically significant. However, Group F had a significantly longer PACU stay than Group S (p=0.01).

Conclusion: Both propofol and fentanyl reduced the incidence of EA after sevoflurane anesthesia, but propofol was associated with a lower rate of nausea and vomiting, making it the preferable option.

I. Introduction

Up to 80% of children experience emergent agitation (EA) in the early stages following sevoflurane anesthesia, making it a common postoperative issue [1,2]. Crying, confusion, excitement, and delirium are some of the behaviors that might be associated with it. While EA is self-limiting and may not have permanent consequences, it poses a risk of self-harm and is stressful for family and careers.[3,4]

Various approaches have been proposed to reduce the frequency and intensity of EA, including the use of sedatives prior to induction, modifications to the maintenance technique of anesthesia, and the administration of

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pharmacological agents during the end of anesthesia [2,5-7]. The use of pharmaceuticals at the conclusion of anesthesia is one of these strategies that is believed to be the most practical and widely used approach among these strategies in clinical settings [2,8,9]. In light of this, it has been demonstrated that administering small dosages of fentanyl or propofol (1 mg kg–1 or 1 ug kg–1) towards the conclusion of anesthesia can effectively lower EA [1,2,10]. We postulated that, under equivalent clinical circumstances, propofol and fentanyl would have differing impacts on reducing the incidence and severity of EA and recovery patterns.

This was a prospective comparative analytic study designed to examine the effects of fentanyl and propofol given after sevoflurane anesthesia on end-of-operative EA in children having orchopexy and inguinal hernia surgery. Additionally, comparisons were made between the anesthesia recovery features and the occurrence of side effects.

II. Methods

This prospective comparative study analysis of 60 children, 12– 60 months of age, ASA class I or II, who were undergoing ambulatory orchiopexy and inguinal surgery under general sevoflurane anesthesia in Aljazeera International Hospital, Misurata, Libya, in the period between January 2023 and April 2024, were prospectively included in this study. Children with one of Exclusion criteria (table 1) were excluded. Prior to the operation, all patients fasted for proper time of his last meal (table 2) and were allowed to consume clear fluids up to two hours beforehand to reduce irritability at induction and may reduce the postoperative nausea and vomiting, the children should not be premeditated before surgery. In this prospective comparative analytic study, patients were divided to 3 groups: with each group to receive either propofol (Group P), fentanyl (Group F), or saline (Group S).

Table 1. Exclusion criteria for subjects

Exclusion Criteria Table 1
Developmental Delay
Psychological Disorder
Neurological Disorder
Abnormal Airway
Reactive Airway Disease
History of General Anasthesia

Table 2. Fasting time required for different types of feeding

Ingested Material	Minimum Fast
clear liquid	2hr
breast milk	4hr
light meal, infant formula, and other milk	6hr

Subjects were observed using non-invasive arterial pressure, electrocardiography, capnography, and pulse oximetry as soon as they arrived in the operating room. anesthesia was induced Using a face mask to inhale 8% sevoflurane in oxygen while monitoring the concentrations of sevoflurane being exhaled and inhaled. A four-point rating system was used to quickly assess the quality of the induction:

1. Loss of Eyelash Reflex: The patient no longer blinks when their eyelashes are gently brushed**. 2**. Jaw Relaxation: The patient's jaw is loose and can be easily opened without resistance**. 3**. Stable Respiration: The patient should have regular, spontaneous breathing with adequate depth**. 4**. No Movement: The patient should not respond to light touch or jaw thrust. These signs indicate that the patient is sufficiently anesthetized and relaxed. An IV cannula was placed and sevoflurane was adjusted to end-tidal 3% and maintained for a few minutes following the loss of consciousness. Once sufficient jaw retraction was achieved, a laryngeal mask airway was placed. the LMA size for individuals weighing should be chosen Table 3. Tracheal intubation was performed and the patient was removed from the research if the LMA insertion failed after three tries.

Table 3. The size of a pediatric laryngeal mask airway (LMA) is typically chosen based on the child's body weight.

Size of laryngeal mask	Weight of patient
Size 1	For infants weighing up to 5 kg
Size 1.5	For infants weighing 5-10 kg
Size 2	For children weighing 10-20 kg
Size 2.5	For children weighing 20-30 kg
Size 3	For children weighing 30-50 kg

Prior to surgery, and during LMA implantation, the individuals were given a caudal block containing 1.2 ml kg^{-1} of 0.5% plain Marcaine. The test for sufficient analgesia of the caudal block was skin incision; if the heart rate went up, 20% within 60 seconds of the skin cut. the block was considered insufficient. In this investigation, only patients with a sufficient caudal block were included. Sevoflurane 2–2.5% in about 50% oxygen was used to maintain anesthesia during the procedure, with a total infusion of Two liters per minute. All subjects maintained spontaneous ventilation.

After the end of procedure, the anesthesia was preserved and the oxygen concentration was changed to 100%. In parallel, the individuals were given, depending on their assigned group, 1 mg kg–1 of propofol, 1 ug kg–1 of fentanyl, or saline over 1min. Following confirmation of normal breathing with a sufficient tidal volume, the LMA was extracted while the patient was sedated. Following removal, patients received 100% oxygen through a face mask, sevoflurane was stopped right away, and they were monitored for at least five minutes to ensure that any potential respiratory complications, such as upper airway blockage, breath holding, or suspected laryngospasm, were managed. Following the resolution of difficulties and confirmation of spontaneous breathing with airway patency without assistance, the participants were sent to the post-anesthesia care unit (PACU).

When the individuals arrived at the PACU, nurses kept an eye on them and provided care. EA and recovery were assessed by two separate investigators (one nurse and one anesthetist). First, after five minutes of arriving at the PACU, the anesthetist measured the time it took for the patient to regain consciousness, which was defined as weeping or opening their eyes in response to a verbal instruction or a gentle touch. For the first thirty minutes after awakening and every five minutes thereafter, the level of agitation was assessed and recorded; the maximum recorded value was utilized for evaluation.

Table 4: The five items assessed in the PAED score.

Item	Score	Sign
Eye Contact	4	=Not making eye contact
	3	= Poor eye contact
	2	=Limited eye contact
	1	=Good eye contact
	0	=Normal eye contact
Purposeful Actions	4	=No purposeful actions
	3	=Poorly purposeful actions
	2	= Limited purposeful actions
	1	=Mostly purposeful actions
	0	=Normal purposeful actions

Item	Score	Sign
Awareness of Surroundings	4 3 2 1 0	=Not aware of surroundings =Poor awareness of surroundings =Limited awareness of surroundings =Mostly aware of surroundings =Normal awareness of surroundings
Restlessness	4 3 2 1 0	=Very restless =Restless =Slightly restless =Calm but not completely still =Calm
Inconsolability	4 3 2 1 0	=Extremely inconsolable =Very inconsolable =Inconsolable =Consolable with difficulty =Easy to console

The PAED (Pediatric Anesthesia Emergence Delirium) score is a tool used to assess the severity of emergence delirium in children recovering from anesthesia (Table4)[2,10]. This score helps healthcare providers identify and manage post-anesthesia emergence delirium, which can be distressing for both the child and caregivers. The PAED score consists of five items, each scored from 0 to 4, with higher scores indicating more severe delirium. The maximum total score is 20

0-4 = No or minimal emergence delirium.

5-9= Mild emergence delirium.

10-14= Moderate emergence delirium.

15-20= Severe emergence delirium.

The five-step EA scale (1, obtunded with no response to stimulation; 2, asleep but responsive to movement or stimulation; 3, awake and responsive; 4, crying; 5, thrashing behaviour that requires restraint) and **Aono's scale** (1, calm; 2, easily consoled state; 3, moderate agitation; 4, severe agitation) were also used to assess EA

The presence of EA was defined as Aono's scale scores ≥ 3 or the five-step EA scale ≥ 4 [2,11-14]. propofol 1 mg kg^{1} was administered as a rescue drug to subjects who had an Aono's scale of 3 or higher for longer than 5 minutes.

when the participants' vital signs were steady, their oxygen saturation was breathing at ambient air is 95% and their airway was patent without assistance, they were moved to the outpatient recovery area and left with their guardian, as per our institute's procedure, subjects had to stay in the outpatient recovery room for a minimum of two hours before being discharged. Throughout the entire recuperation phase, the incidence of nausea or vomiting was monitored and managed with ondansetron 0.1 mg kg. Along with documenting the length of the PACU stay, the delayed discharge from the outpatient recovery area, and any adverse events such somnolence, delayed voiding, nausea, or vomiting, the anesthetist who assessed the PAED scale also kept track of these details.

Ethical Approval:

Ethical approval for this study was obtained from the administration of Al-Jazeera International Hospital. Verbal consent was also obtained from the parents of the patients to allow the use of their medical data for this research. All data were handled with strict confidentiality, ensuring that the identities of the patients or any personal information were not disclosed.

Statistical analysis

According to earlier research, the frequency of EA under efficient planned techniques was between 10% and 20%. The data was presented as frequencies (percentages) or as means standard deviation of the mean The x2 test was used to analyze categorical data, such as the incidence of EA, which were provided as percentages and numbers. A P-values are calculated using The Student's t test to compare the means between two groups, whereas ANOVA is used to compare the means among three groups A statistically significant P-value was set at< 0.05.

III. Results

Sixty of the 80 patients who were originally evaluated successfully finished the investigation. Table 5 indicates that there were no statistically significant variations in the three groups' age, weight, gender, or anaesthesia duration.

Group P's and Group F's mean PAED score values, respectively, were considerably lower than Group S's value, [14] (P,0.001), and there was no significant difference between Groups P and F (P=0.715), Fig 1. Additionally, Aono's scale (Fig.2) and the five-step EAS (Fig 3) demonstrated that comparable to Group S, the incidence of EA in Groups P and F was significantly lower (P< 0.001)

Table 5 shows Group F subjects spent 36 ±1.32minutes in the PACU, whereas Group S subjects only spent 34.8± 1.32 minutes there (P= 0.001). Nonetheless, no statistically significant variation was seen in the length of PACU stay between Groups F and P (35± 1.86min) (P=0.06) or between Groups P and S (P=0.8). After being admitted for 2 hours to the outpatient recovery room, all participants were released.

As in table 5, propofol was used more frequently in Group S as rescue medication for EA than other two groups (adjusted P,0.001). Group F had a significantly higher incidence of nausea and vomiting than Group P or S, with 30% of subjects in Group F requiring antiemetic medication (P=0.001). one subject from Group P and two from Group F required jaw thrust for the maintenance of upper airway patency, and four subjects (two from group P and two from group F) presented with suspicious laryngospasm, which was resolved by continuous positive pressure ventilation.

Table 5. Comparison between the three groups: (p) Propofol; (f) Fentanyl; (s) Saline

Type of group	(P) Propofol	(F) Fentanyl	(S) Saline	Test of significance
Sample size	(*n*=20)	(*n*=20)	(*n*=20)	N.S
Age(yr) mean(range)	3.3 (1–5.6)	2.9 (1.5–5.0)	2.8 (1.2-4.9)	N.S
Weight (kg) mean (SD)	16.4 (2.8)	15.8 (2.12)	16.2 (2.5)	N.S
Gender (M/F) (%)	13 (62)/8 (38)	11 (55)/9 (45)	12 (57)/9 (43)	N.S
PAED score mean (SD)	5.05(1.11)	5.2(0.88)	14(1.45)	**P-F**(P-(value=0.715 **p-S** (p-valu<0.001) **F-S**(p-value<0.001)
PACU duration (min) mean (SD)	35(1.86)	36 (1.32)	34.8(1.32)	**P-F**(p-value=0.06) **P-S**(p-value=0.8) **F-S**(p-value<0.01)

Type of group	(P) Propofol	(F) Fentanyl	(S) Saline	Test of significance
Time for awakening (min)	27.7 (8.5)	30.5 (12.3)	17.6 (11.9)	**P-F**(p-value=0.08) **P-S**(p-value=0.9) **F-S**(p-value<0.01)
Nausea or vomiting mean (SD)	0.2(0.42)	0.75(0.39)	0.1(0.3)	**P-F** (p-value<0.001) **P-S**(p-value>0.1) **F-S**(p-value<0.001)
Onansteron use	1(5%)	6(30%)	1(5%)	**P-F** (p-value<0.001) **P-S**(p-value>0.1) **F-S**(p-value<0.001)
Propofol use	1(5%)	0(0%)	5(25%)	**P-F** (p-value>0. 1) **P-S**(p-value<0.01) **F-S**(p-value<0.001)

Abreviations: NS, non-significant; SD, standard deviation

Using unpaired Student's t-test ; statistically significant P-value was set at< 0.05.

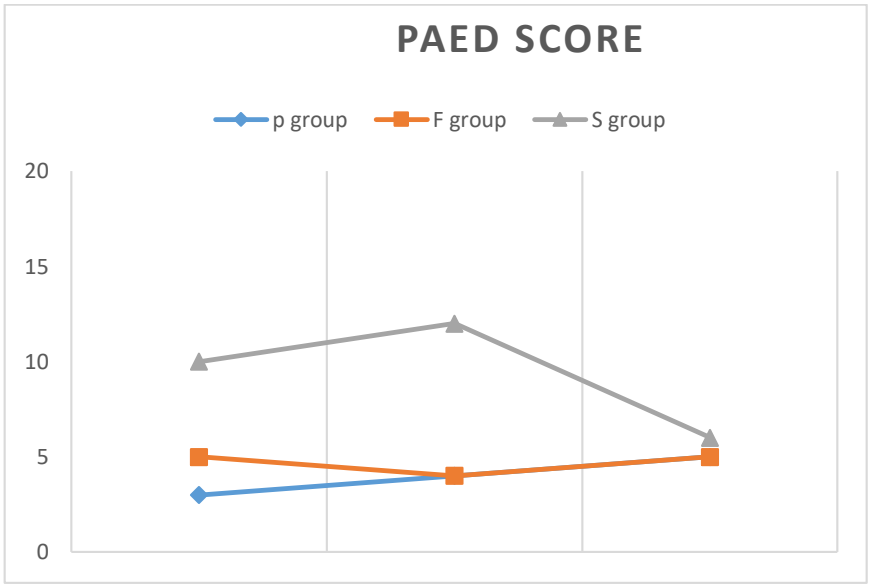

Fig 1. Distributions of the PAED score. PAED, pediatric anaesthesia emergence delirium; P, propofol; F, fentanyl; S, saline.

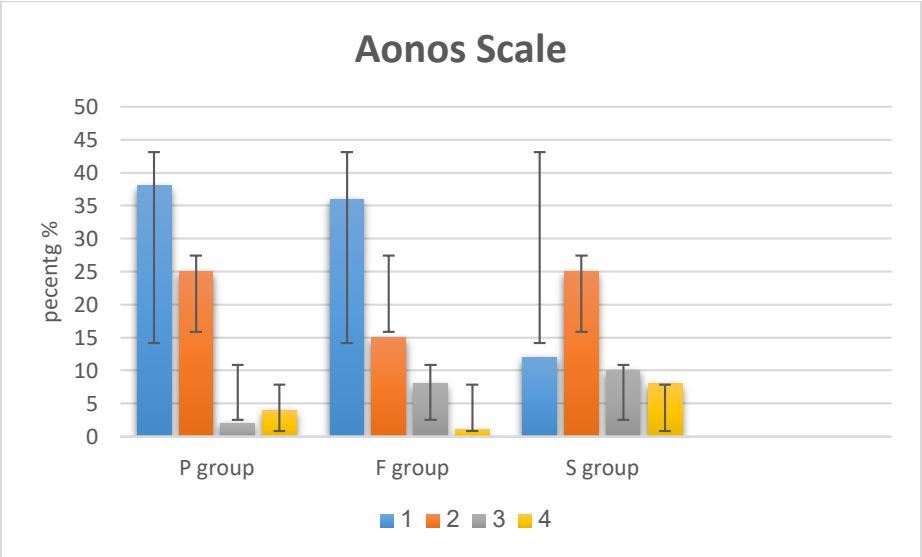

Fig. 2 Distributions of scores according to Aono's scale P, propofol; F, fentanyl; S, saline.

Aono's scale (1, calm; 2, easily consoled state; 3, moderate agitation; 4, severe agitation)

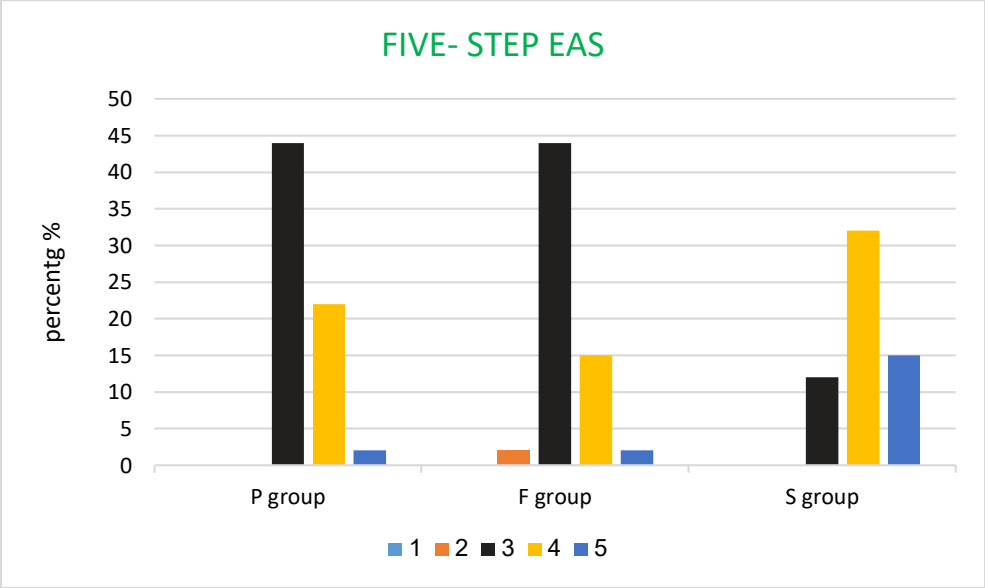

Fig 3. The five-step EAS. EAS, emergence agitation scale (1, obtunded with no response to stimulation; 2, asleep but responsive to movement or stimulation; 3, awake and responsive; 4, crying; 5, thrashing behaviour that requires restraint).

IV. Discussion

In comparison to saline, the injection of 1 mg kg of propofol or 1 ug kg of fentanyl at the conclusion of sevoflurane anaesthesia was found to be equal in lowering (EA). Additionally, patients who got propofol experienced less vomiting than those who received fentanyl. Moreover, fentanyl prolonged the PACU stay when compared to saline; however, Group P did not experience this effect. Nevertheless, it was determined that there was no clinically meaningful difference in the length of PACU stay between Groups P and F.

Although many agents have been studied in an attempt to lower the incidence of EA, the results have been inconsistent. Several drugs have been shown to have preventive effects, including ketamine, fentanyl, propofol, and an agonist for the a2-adrenergic receptor. It was unclear how effective a particular medication was in comparison to others. In one recent trial were carried out specifically to compare two or three medications administered at the conclusion of anaesthesia. When propofol, midazolam, or ketamine were used in conjunction with fentanyl immediately following the cessation of sevoflurane anaesthesia in paediatric cataract surgery patients, Chen et al [15]. found that both of these combinations were useful in lowering EA. However, because fentanyl is believed to reduce the incidence and severity of EA independently of its analgesic effect, the effects of propofol or midazolam on EA are additive or synergistic with it. [10,16].

There is a need for more comparative research with different pharmacological combinations and clinical scenarios. Therefore, we compared the two drugs that are most frequently researched in the field of EA, propofol and fentanyl, in patients having orchopexy and inguinal hernia repair surgery.

Children are routinely given propofol to induce and sustain general anaesthesia[17-19] Propofol's pharmacokinetic qualities provide for a smoother recovery profile in children as compared to sevoflurane during anaesthesia maintenance as opposed to induction [6,8,20]. In paediatric anaesthesia, however, induction is typically accomplished without the need for intravascular access.

Thankfully, a number of studies have demonstrated that in children receiving sevoflurane for anaesthesia induction and maintenance, a single dose of 1 mg kg of propofol at the end of anaesthesia is useful in lowering EA without delaying departure from the PACU[1,2], fentanyl offers an additional choice. In one earlier investigation, the impact of fentanyl on EA was assessed at a dose lower than that which was used to induction in children following sevoflurane anaesthesia without surgery (1 ug kg); the incidence of EA was reduced regardless of its analgesic effects, and the time to reach homeostasis was also shortened[10].

Therefore, even in the absence of significant postoperative pain, supplementing sevoflurane anaesthesia with a small dose of fentanyl can still be considered help to reduce the incidence and severity of EA. Our findings showed that propofol and fentanyl were equally effective at reducing the incidence and severity of EA following sevoflurane anaesthesia.

In spite of the two medications' similar abilities to reduce the frequency and severity of EA, we discovered that the fentanyl group had a significantly higher incidence of nausea or vomiting (Group F 30% compared to Group P's 5%) While all patients stay in the out-patient recovery room for a minimum of two hours in accordance with our institute's protocol, the occurrence of postoperative vomiting in this study did not result in a delayed discharge.

A further issue with administering fentanyl and propofol near the end of anaesthesia is the potential for delayed emergence. Compared to a placebo, propofol and fentanyl both prolonged the time it took to wake up by more than ten minutes. On the other hand, after waking up for 15 minutes, the kids in Groups P and F were moved from the PACU to the outpatient recovery room, while Group S's kids needed more than 20 minutes to be released from the facility. Consequently, a little delayed awakening following the administration of propofol or fentanyl may not result in a clinically significant delay in discharge from the PACU.

Postoperative pain is a well-known cause of postoperative distress and agitation in children, even though EA following sevoflurane anaesthesia can occur in pain-free patients. Because of this, it is best to study how anaesthetic procedures affect EA in the absence of post-surgical pain. In our investigation, a caudal block was used to both treat postoperative pain and rule out the possibility that it contributed to the development of EA. According to certain earlier research, caudal block administered prior to surgery in children under sevoflurane anaesthesia

can reduce the incidence and severity of E.A. The incidence of E.A in subjects who have caudal block can range from 4.5% to 26% [21].

While parental presence in the PACU and the use of mid-azolam as a premedication were not employed in our investigation, it is possible that these factors contributed to the reduced incidence of EA [21].

An impartial comparison of two medications should be conducted using a dependable scale or scoring method to determine whether EA is present. The incidence of EA may vary depending on the assessment instruments, as prior research has employed scales other than the PAED scale [12]. Propofol and fentanyl have shown similar efficacy in the prevention of EA by all three scales, hence we used not only the PAED scale but also the two extra scales.

There are multiple restrictions on our investigation. Our initial research focused on single children undergoing inguinal hernia or orchiopexy surgery. Otorhinolaryngological and ophthalmological operations are known to have a higher incidence of E.A than other types of surgery. This suggests that the efficacy of propofol and fentanyl in this trial may vary depending on the type of surgery. Nevertheless, we could carry out the clear comparison if we restricted the kind of operation eradication of the surgical effects on EA following the administration of both medications.

Second, this study did not include children who had significant anxiety prior to surgery. Considering that preoperative anxiety has been shown to both cause and worsen EA, further research on the effects of fentanyl and propofol on EA in these patients may prove clinically advantageous.

Thirdly, since there may be late-onset nausea or vomiting, the absence of follow-up beyond discharge may pose a constraint on how these study results are interpreted.

Despite this, we were able to validate the benefit of propofol with regard to nausea or vomiting due to the statistically significant difference in the frequency of these symptoms between propofol and fentanyl (5% vs. 25%) during the recovery period.

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Conflicts of Interest:

None declared.

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V. Conclusion:

The incidence of EA was effectively decreased by using either propofol or fentanyl when sevoflurane anaesthesia was stopped; propofol may be preferred due to the decreased incidence of vomiting.

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