

## THE EFFECT OF FENTANYL VS KETAMINE ON THE INCIDENCE OF EMERGENCE DELIRIUM FROM SEVOFLURANE ANESTHESIA IN PEDIATRIC PATIENT UNDERGOING TONSILLECTOMY

G Shanmugapriya<sup>1</sup>, S Ramya<sup>2</sup>, Jeyalakshmi Venkatesan<sup>3</sup>

<sup>1</sup>Assistant Professor, Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai, Tamil Nadu, India

<sup>2</sup>Senior Resident, Government Kallakurichi Medical College, Kallakurichi, Tamil Nadu, India

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Corresponding Author:

Dr. G Shanmugapriya,

Email:

drshanmugapriya.official@gmail.com

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### ABSTRACT

**Background:** Emergence delirium has been documented as a common side effect of sevoflurane anesthesia. This prospective, randomized, double blind, study was designed to compare the effects of Ketamine versus Fentanyl, administered 10 mins before the end of surgery on the development of emergence delirium. **Material & Methods:** A total of 40 children aged 5-12 years of American Society of Anesthesiologists 1 & 2 physical status were randomly assigned to one of two groups receiving either ketamine 0.5 mg/kg (Group K), or fentanyl 1 µg/kg (Group F) at 10 min before the end of surgery. Post-operative emergence delirium was assessed with Aono's four point scale. Recovery times, the post-operative pain and adverse reactions were assessed. **Results:** The incidence of emergence delirium assessed by Aono's four point scale is low in both Fentanyl and Ketamine group with the score < 2 at all times. Time of emergence, time of extubation and time to recovery is longer with Ketamine group when compared to Fentanyl group with a p value of 0.002. The post operative pain assessed by CHEOPS scale is higher in Ketamine group at 10, 20 and 30 minutes when compared to Fentanyl group with a p value of < 0.05. As of complications is concerned one patient had vomiting in both the groups and one patient in ketamine group had bronchospasm. 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:** Both Fentanyl and Ketamine are effective in decreasing the occurrence of emergence delirium. However Fentanyl has faster emergence, extubation, recovery and better pain score when compared to Ketamine.

## INTRODUCTION

Several studies have revealed that sevoflurane anesthesia even though having the advantage of rapid emergence and recovery has been associated with emergence delirium in pediatric age group. Several drugs has been investigated to reduce the occurrence and the severity of emergence delirium with variable outcome. These include propofol, fentanyl, ketamine,  $\alpha_2$  agonists like clonidine, dexmedetomidine and they are found to be effective in decreasing the incidence of emergence delirium.<sup>[2]</sup>

Emergence delirium is a transient confusional state that is associated with emergence from general anesthesia. Emergence excitement is common in children, with an incidence of more than 30%. It usually occurs within the first 10 minutes of recovery but can have later onset in children who are brought

to the recovery room asleep. Peak age of incidence is less than 5 yrs.<sup>[8]</sup>

Child with emergence delirium appears wild and incoherent. They are inconsolable and does not appear to recognize familiar people. It usually lasts for 5- 15 minutes, self limiting, resolves quickly and is followed by an uneventful recovery. Even though it is usually self-limited; emergence delirium is still considered as worrisome 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 and increase in need for continuous monitoring of patients by recovery room staffs and physical restraint of patient.

In children, emergence excitement is most frequently associated with rapid "wake up" from inhalational anesthesia. Although it has also been reported after isoflurane and, to a lesser extent, halothane anesthesia, emergence excitement is most often

associated with the less-soluble vapors, sevoflurane and desflurane. There is 33% higher incidence of excitement during emergence (~21% versus ~15%) with sevoflurane anesthesia when compared to halothane. Incidence of emergence excitement is more a reflection of the anesthetic agent used rather than the rapidity of emergence.<sup>[1]</sup>

#### **Aim of the Study**

To compare the efficacy of Fentanyl 1 $\mu$ /kg and Ketamine 0.5 mg/kg administered 10 minutes before the end of surgery for the development of emergence delirium and recovery profile in pediatric patients undergoing tonsillectomy.

## **MATERIALS AND METHODS**

### **Study Design**

Prospective, randomized, double blinded study  
The study was started after receiving Institutional Ethical Committee approval and written informed consent from all the patients.

### **Randomization**

Simple randomized sampling was done by computer generated random numbers.

### **Group-Allocation**

Patients were allocated into two groups  
Group F (n= 20): Patients receiving Fentanyl  
Group K (n= 20): Patients receiving Ketamine

### **Blinding**

Study drugs are prepared by an anesthesiologist not involved in the study. Anesthesiologist who observe the patient is unaware of the study group until the end of the study.

### **Inclusion Criteria**

- Age 5 to 12 years
- ASA I & II
- Written informed consent

### **Exclusion Criteria**

- Patient refusal
- ASA grade III and IV
- Patients with h/o sleep apnoea
- Cognitive or developmental disorder
- Patients on sedative medication
- Neurological condition that may limit patient's ability to communicate with or understanding nursing personnel.
- Patients requiring additional dose of muscle relaxant

### **Materials**

- Drugs for the study
- Monitor – Philips Sure Signs VM8 – ECG, Pulse Oximeter, Non Invasive Blood Pressure, Capnograph.
- Equipment & drugs for resuscitation

### **Methods**

#### **Pre operative preparation**

The patients were pre operatively assessed; their parents were explained about the purpose of the study and about the possible adverse events that can occur due to the study drug, and written informed consent

was obtained from those parents who were willing to allow their ward to take part in the study.

### **Conduct of Anaesthesia**

On arrival of the patient in the operating room, monitors – Pulse oximeter, Non Invasive Blood Pressure (NIBP) and ECG were connected and baseline values were recorded.

### **IV access is established**

Patient is premedicated with Inj Atropine 15 $\mu$ /kg, Inj Fentanyl 2 $\mu$ /kg, Inj. Midazolam 0.15mg/kg. Anesthesia is 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%.

Inj.Dexamethasone 0.3mg/kg and Inj.Ondansetron 0.1mg/kg iv is given after induction. Tracheal intubation is facilitated with Inj.Atracurium 0.5 mg/kg. General anesthesia is maintained with O<sub>2</sub> and N<sub>2</sub>O 50:50, sevoflurane 1% with controlled ventilation. Paracetamol suppository 15mg/kg is kept after induction.

Before the start of surgery, the surgeon infiltrates the operative site with 1% lidocaine for pain control.

The study drug is prepared and diluted to 5ml by an anaesthesiologist not participating in the study

In GROUP F, patients received 1 $\mu$ g/kg of fentanyl 10 min before the end of surgery, (n=20).

In GROUP K, patients received 0.5mg/kg of ketamine 10 min before the end of surgery, (n=20).

Intra operatively hemodynamic variables like heart rate, blood pressure, oxygen saturation, EtCO<sub>2</sub> is monitored

The study drug is given by the anesthesiologist not participating in the study 10 minutes before the end of the surgery. At the end of surgery, once hemostasis is achieved, the inhalational anesthetics is discontinued and patient is ventilated with 100% oxygen at 6 L/min.

After onset of spontaneous respiration, the neuro muscular blockade is reversed with Inj.Neostigmine 0.05mg/kg and Inj.Atropine 20  $\mu$ g/kg.

After thorough oropharyngeal suctioning, after return of sufficient spontaneous breathing, gag reflex, facial grimaces and purposeful motor movements, patient is extubated and put in recovery position

### **Parameters Monitored**

Emergence Time is defined as the time of first response to command or eye opening on command after discontinuation of inhalational anesthetics.

Time to extubation is defined as time from the end of surgery to tracheal extubation.

Duration of surgery is recorded as the time between the insertion and removal of the mouth gag.

Duration of anesthesia is recorded as the time from induction until the extubation.

All patients were observed continuously for at least 30 min post operatively.

The primary outcome of the study is the incidence of post-operative emergence delirium, which is 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 (4) agitated and difficult to console

Grades 1 and 2 in the scale of behavior are considered as no agitation and Grades 3 and 4 are considered the presence of agitation.

S.No	Parameter	Category	Score
1	CRY	No cry	1
		Moaning	2
		Crying	3
		Screaming	4
2	FACIAL	Smiling	0
		Composed	1
		Grimace	2
		Positive	0
3	VERBAL	None	1
		Complaints other than pain	1
		Pain complaints	2
		Pain & non-pain complaints	2
4	TORSO	Neutral	1
		Shifting	2
		Tense	2
		Shivering	2
		Upright	2
		Restrained	2
		Not touching	1
5	TOUCH	Reach	2
		Touch	2
		Grab	2
		Restrained	2
6	LEGS	Neutral	1
		Squirming, kicking	2
		Draw up tensed	2
		Standing	2
		Restrained	2
Minimum score – 4			
Maximum score – 13			

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 is used for post-operative pain assessment and it is measured at 5, 10, 20 and 30 min post-operatively

**Discharge criteria**

1. being fully awake,
2. stable vital signs for 30 min,
3. no bleeding,
4. no pain,
5. no nausea or vomiting and
6. able to ambulate according to age

Children were considered ready for discharge from the recovery room when the modified Aldrete post-anesthesia score is  $\geq 9.1$

Time to recovery is recorded as the time from extubation to reach the modified aldrete score of  $> 9$  Patients who fulfill the discharge criteria are transferred to PACU and the recovery room stay time is recorded.

**Adverse events**

1. vomiting

**A: Demographic Data**

**Table 1: age distribution (years)**

Parameter	Group F	Group K
Mean	9.45	9.00
Std Deviation	2.01	2.38
P Value	0.523	

2. oxygen desaturation
3. somnolence and
4. hallucination incidence are also recorded

**RESULTS**

The data collected from all the selected cases were recorded and tabulated in a Master Chart.

**Statistical Tools**

Statistical analysis was performed with the help of statistical package IBM-SPSS version 20.0 (IBM-SPSS Science Inc., Chicago, IL).

Baseline characteristics of both the groups were tabulated by descriptive statistics (mean , standard deviation) and frequency table.

Continuous data were compared by Independent sample t test

Chi square test was used to find out association between collected categorical data.

Significance was defined by P values less than 0.05

**Results**

GROUP F: Fentanyl group

GROUP K: Ketamine group.

The two groups are matched according to their weight and found that both groups are comparable (9.45± 2.01 in fentanyl group vs 9.00±2.38 in

ketamine group) and the data are statistically not significant with a p value 0.523. (p> 0.05)

**Table 2: Weight (KG)**

Parameter	Group F	Group K
Mean	25.55	23.95
Std Deviation	6.86	6.09
P Value	0.44	

The two groups were matched according to their weight and found that both the groups are comparable (25.55±6.86 in fentanyl group vs 23.95±6.09 in

ketamine group) and the data are statistically not significant with a p value 0.44. (p > 0.05).

**Table 3: duration of surgery (minutes)**

Parameter	Group F	Group K
Mean	32.95	31.65
Std Deviation	7.39	5.16
P Value	0.523	

Duration of surgery is recorded as the time between the insertion and removal of the mouth gag.

The two groups were matched according to the duration of surgery and found that they are

comparable (32.95±7.39 in fentanyl group vs 31.65±5.16 in ketamine group) and the data are statistically not significant with a p value of 0.523. (p>0.05)

**Table 4: duration of anesthesia (minutes)**

Parameter	Group F	Group K
Mean	61.20	63.15
Std Deviation	8.67	11.24
P Value	0.543	

Duration of Anesthesia is recorded as the time from induction until the extubation.

The two groups were matched according to the duration of Anesthesia and found that they are comparable (61.20±8.67 in fentanyl group vs 63.15±11.24 in ketamine group) and the data are statistically not significant with a p value of 0.543. (p>0.05)

#### **B. Time of emergence**

Emergence Time is defined as the time of first response to command or eye opening on command after discontinuation of inhalational anesthetics

Parameter	Group F	Group K
Mean	7.60	11.35
Std Deviation	3.52	3.48
P Value	0.002	

The two groups were matched according to the time of emergence and found that there was significant difference in their mean values (7.60±3.52 in fentanyl group vs 11.35±3.48 in ketamine group) and the data

are statistically significant with a p value of 0.002. (p>0.05)

#### **C. Time of Extubation**

Time to extubation is defined as time from the end of surgery to tracheal extubation.

Parameter	Group F	Group K
Mean	10.75	14.85
Std Deviation	3.32	4.38
P Value	0.002	

The two groups were matched according to the time of extubation and found that there is significant difference in their mean values (10.75±3.32 in fentanyl group vs 14.85±4.38 in ketamine group) and the data were statistically significant with a p value of 0.002. (p>0.05)

#### **D. time to recovery**

Time to recovery is recorded as the time from extubation to reach the modified Aldrete score of > 9

Parameter	Group F	Group K
Mean	22.00	25.15
Std Deviation	2.38	3.39
P Value	0.002	

The two groups were matched according to the time to recovery and found that there is significant difference in their mean values (22.00±2.38 in fentanyl group vs 25.15±3.39 in ketamine group) and the data are statistically significant with a p value of 0.002.(p>0.05)

#### E.Emergence Delirium

Emergence delirium was assessed using Anso's four point scale at 5,10,15,20 and 30 minutes. The score

of 3 and 4 are considered as presence of emergence delirium.

The two groups were matched according to the emergence delirium occurrence by Anso's four point scale and found that they were statistically not significant at all times. The mean values in both groups are less than 2 and the p value is >0.05 at all times.

Time (min)	Group	Mean	Std. Dev	P value
ANO 5	F	1.55	0.83	0.304
	K	1.85	0.99	
ANO 10	F	1.65	0.75	0.145
	K	2.05	0.94	
ANO 15	F	1.80	0.41	0.251
	K	2.00	0.65	
ANO 20	F	1.95	0.22	1.000
	K	1.95	0.51	
ANO 30	F	2.00	0.00	0.324
	K	2.05	0.22	

#### F.Cheops (Children's Hospital of Eastern Ontario Pain Scale)

The post operative pain is assessed with CHEOPS at 5,10,15,20 and 30 minutes interval

Time (min)	Group	Mean	S.D	P value
CHEO 5	F	6.25	1.97	0.131
	K	7.25	2.12	
CHEO 10	F	5.75	1.74	0.031
	K	7.25	2.43	
CHEO 20	F	5.45	0.83	0.05
	K	6.45	2.14	
CHEO 30	F	5.40	0.82	0.031
	K	6.50	2.04	

The post operative pain were compared according to the CHEOPS in two groups and found that there is higher scores in Ketamine group at 10,20 and 30 minutes. There is significant difference at 10 minutes (5.75±1.74 in Fentanyl group vs 7.25±2.43 in Ketamine group) with a p value of 0.031, at 20 minutes(5.45±0.83 in Fentanyl group vs 6.45±2.14 in Ketamine group) with a p value of 0.05 and at 30 minutes (5.40±0.82 in Fentanyl group vs 6.50±2.04 in Ketamine group) with a p value of 0.031 with greater scores in Ketamine group which is statistically significant.

#### Summary

To summarise, both Fentanyl and Ketamine are effective in decreasing the occurrence of emergence delirium.

Time of emergence, time of extubation and time to recovery is longer with Ketamine when compared to Fentanyl.

The post operative pain assessed by CHEOPS scale is higher with Ketamine at 10, 20 and 30 minutes when compared to Fentanyl.

As of complications is concerned, one patient had vomiting in both the groups and one patient in Ketamine group had brochospasm.

## DISCUSSION

Several studies had been conducted comparing different agents for decreasing the incidence of emergence delirium from sevoflurane anesthesia. They also studied the pain score, time of emergence, time of extubation, time to recovery and occurrence of complications like laryngospasm, nausea, vomiting, respiratory depression, hallucination, etc with the use of those agents. Many studies had compared different doses of fentanyl and ketamine for reducing emergence delirium

In our study, Fentanyl is compared with Ketamine with regards to incidence of emergence delirium ,pain , time of emergence, time of extubation, time to recovery and occurrence of complications from sevoflurane anesthesia in pediatric patients undergoing tonsillectomy surgery. In our study, the demographic data such as age, weight, duration of surgery were comparable between both the groups.

In the study conducted by Ashraf Arafat et al<sup>[1]</sup> where 120 patients were studied for the effect of fentanyl vs ketamine on the incidence of emergence delirium from sevoflurane anesthesia in patients undergoing tonsillectomy and concluded that the incidence of Emergence delirium was significantly less in children who received either ketamine or fentanyl (15%, 17.5%) when compared to the incidence of

emergence delirium in placebo group (42.5%). But in our study we assessed the incidence of emergence delirium with ANO'S four point scale and observed that both fentanyl and ketamine were effective in decreasing the occurrence of emergence delirium. The datas obtained from both the groups were comparable at all time intervals and the values were less than 2 at all times and they are statistically not significant with a p value of  $> 0.05$

As regard to post-operative pain assessment, in our study the pain score assessed with CHEOPS is found to be higher in ketamine group at 10,20 and 30 minutes. There is significant difference at 10 minutes ( $5.75 \pm 1.74$  in fentanyl group vs  $7.25 \pm 2.43$  in ketamine group) with a p value of 0.031, at 20 minutes ( $5.45 \pm 0.83$  vs  $6.45 \pm 2.14$  in ketamine group) with a p value of 0.05 and at 30 minutes ( $5.40 \pm 0.82$  in fentanyl group vs  $6.50 \pm 2.04$  in ketamine group) with a p value of 0.031 which is statistically significant. But in their study there was no significant difference between the three groups at 5,10,20 and 30 min post-operatively

In their study there was no significant difference between the three groups regarding recovery and discharge times. But in our study recovery time was prolonged in Ketamine group ( $25.15 \pm 3.39$ ) than in fentanyl group ( $22.00 \pm 2.38$ ) and the datas are statistically significant with a p value of 0.002. ( $p < 0.05$ ). Similarly in contrast to their study the time of emergence (Group K  $11.35 \pm 3.48$  vs Group F  $7.60 \pm 3.52$ ), and the time of extubation (Group K  $14.85 \pm 4.38$  vs Group F  $10.75 \pm 3.32$ ) is also prolonged in Ketamine group when compared to Fentanyl group and they are statistically significant with a p value of 0.002

In their study post-operative fentanyl consumption as rescue medication for pain and agitation was significantly more in placebo group when compared with ketamine and fentanyl group, with no significant difference between fentanyl and ketamine group.

Manal et al<sup>[7]</sup> in their study compared the effect of intravenous injection of small dose of propofol, fentanyl or ketamine at the end of surgery, just before the discontinuation of sevoflurane on the incidence and severity of sevoflurane emergence agitation in children undergoing hypospadias repair operations. In their study the incidence of emergence agitation was significantly lower in propofol and fentanyl group when compared to ketamine and control group. Consistent with this study the number of patients with emergence delirium is higher in ketamine group (8 pts out of 20 pts) when compared to fentanyl group (4 pts out of 20 pts) in our study also but the results were not statistically significant.

Ketamine was reported to have been used successfully to reduce the incidence of emergence delirium in a study conducted by Dalens et al. and they reported that the IV administration of 0.25 mg/kg of ketamine or nalbuphine 0.1mg/kg before discontinuing of sevoflurane anesthesia reduced incidence of emergence delirium 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<sup>[1]</sup> 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 emergence delirium under general anesthesia with sevoflurane without a delay in recovery.

However, conflicting results have been reported by Chen et al.<sup>[4]</sup> 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-remifentanyl based anesthesia was not effective in preventing emergence delirium in un-pre-medicated children who underwent cataract surgery compared to either 0.05 mg/kg midazolam or 1 mg/kg x propofol in combination with 0.5 mcg/kg of fentanyl.

Fentanyl is a potent opioid receptor agonist, widely used and seems to be effective in preventing emergence delirium. Cravero et al.<sup>[5]</sup> 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. In our study also administration of 1 mcg/kg fentanyl towards the end of sevoflurane anesthesia decreases the incidence of emergence delirium which correlates with this study.

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 study drugs and lastly criteria used to define and assess the phenomenon of emergence delirium by different assessment tools.

The time interval for measuring the incidence of emergence delirium, was chosen to be within 30 min during PACU stay according to results of Cole et al.,<sup>[10]</sup> who scored children every 10 min on arrival in PACU up to 1 hr 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 emergence delirium in younger children as symptoms of both are 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 emergence delirium there are many studies reporting the increased incidence of emergence delirium after sevoflurane, in pain-free children even if adequate analgesia given intra-operatively or even if regional block was applied. Therefore, pain cannot be considered as the sole contributing factor to emergence delirium.

In our study pain was probably not a contributing factor in the incidence of emergence delirium, as Paracetamol suppositories was kept in all children

after induction of anesthesia and the surgeon infiltrated the surgical site with 1% lignocaine.

As of complications is concerned one patient had vomiting in both the groups and one patient in ketamine group had bronchospasm. 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 supporting the findings reached by Dich-Nielsen et al.<sup>[6]</sup>

Limitations of our study is that control group has not been included in our study since it was not approved in our institutional ethical committee. So the study groups could not be compared for the incidence of emergence delirium.

## CONCLUSION

To conclude both Fentanyl and Ketamine are effective in decreasing the occurrence of emergence delirium. However Fentanyl has faster emergence, extubation, recovery and better pain score when compared to Ketamine.

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