

## Original Research

### Complications of Sevoflurane-Fentanyl Versus Propofol-Fentanyl Based Anesthesia in Pediatric Cleft Lip And Palate Surgery

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#### ABSTRACT:

**Introduction:** The careful choice of anesthetic agents in pediatric anesthesia reduces the frequency of anesthesia related complications. The objective of this study was to compare the intra operative and postoperative complication rates of propofol based anesthesia versus sevoflurane based anesthesia in cases of pediatric cleft lip, palate, alveolus surgery. **Material and methods:** 77 children from age group of 6months -12 years undergoing cleft lip, palate and alveolus surgeries were included in the study. They were divided in two groups, propofol group (n=37) were induced with propofol (2-3mg/kg), fentanyl (2µg/kg) and vecuronium (0.1mg/kg), the anesthesia was maintained with propofol according to defined parameters. Sevoflurane-fentanyl group (n=40) was induced (5-8%) and maintained (0.8-1%) sevoflurane, supplemented with vecuronium and fentanyl. Both groups demographic data, hemodynamics and respiratory parameters were compared. **Results:** Hemodynamic parameters (Hb, HR) and SpO<sub>2</sub> showed no significant difference in both groups. Emergence agitation was significantly higher in sevoflurane group (n=11) as compared to propofol group (n=3). There were more reported cases of nausea/vomiting in sevoflurane group (n=12) as compared to propofol group (n=2) **Conclusion:** Propofol based anesthesia is safer than Sevoflurane based anesthesia regarding occurrence of emergence agitation and nausea/vomiting

**Key words:** Propofol, Sevoflurane, Cleft lip and Palate

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#### INTRODUCTION

Cleft lip and palate is one of the commonest congenital deformities. The associated facial disfigurement causes feeding, speech and dental development problems and has significant psychosocial consequences. Surgery aims to restore form and function. Airway management problems dealing with associated abnormalities and young patients present anesthetic challenges. Cleft lip/palate is also associated with an increased incidence of congenital abnormalities in other organ which are of anesthetic importance. Multiple out-patient appointments, and possibly operative procedures, are necessary, extending from infancy into adolescence, which are life changing for the patient.

Despite cleft repair being a relatively common operation worldwide, there are only few prospective studies comparing different anesthetic techniques. Some complications such as bleeding, change in endotracheal tube position or post operative swelling are attributed to surgical procedures, others like problems in airway management, post operative nausea, vomiting and emergence agitation may be associated with choice of anesthesia. Various anesthetic techniques have been proposed to reduce the rate of complications associated with anesthesia. There are only few consensus are available about the safety of various anesthetic agent for pediatric age group undergoing cleft surgeries. Sevoflurane as inhalational anesthetic agent is being routinely used

since 1990's for anesthesia in pediatric age group undergoing cleft surgeries. It is associated with fewer complications as compared to other inhalational anesthetics such as halothane or isoflurane due to low blood solubility, but the absolute safety of sevoflurane has not been confirmed consistently. Sevoflurane, with its low pungency and low blood and tissue solubility, is an attractive anesthetic agent in pediatric outpatient surgery.

Propofol has become a good choice for intravenous induction of anaesthesia in pediatrics. Propofol based anesthesia is recognized for its rapid and clear-headed emergence. The choice of anesthetic agent mainly depend on preference of anesthesiologist. Two techniques majorly used in pediatric anesthesia are intravenous (midazolam, propofol) or inhalational (sevoflurane, isoflurane, desflurane) along with muscle relaxant and analgesics.

With this background a randomized comparative study was conducted to compare complications of sevoflurane –fentanyl versus propofol – fentanyl group in pediatric cleft lip palate and alveolar bone grafting surgeries.

**AIMS AND OBJECTIVES**

1. To compare the intra operative and post operative complication rates of propofol based anesthesia versus sevoflurane based anesthesia in Pediatric cleft lip, palate and alveolus surgeries.
2. To compare effects of propofol and sevoflurane on hemodynamic parameters (Hb, heart rate, SpO<sub>2</sub>).

**METHODOLOGY**

The study was conducted on patients with cleft lip palate and alveolus reporting to A.B. Shetty Memorial Institute of Dental Sciences, Mangalore operated in K.S Hegde Hospital. 77 patients with cleft lip, palate and alveolus were included in the study which were randomly allocated to propofol (n=37) and sevoflurane group (n=40). **Methods of collection of data:** Pre operative, intra operative and post operative values of oxygen saturation (SpO<sub>2</sub>) and heart rate (HR) were recorded. Hemoglobin preoperatively was also assessed. Preoperative data was collected 5 min before induction. Intra operative and post operative oxygen saturation and heart rate were measured every 10 minutes. The intra operative and post operative complications were recorded.

Inclusion criteria	Exclusion criteria
Patients in need of surgical correction of cleft deformity	Patients with infection or asthma
Age group of 6months-12 years	Patients with anemia
	Patient with severe heart defects or mental retardation.

**Methodology :** All pediatric patients scheduled for elective cleft lip, palate and alveolus surgery were included in study. **Pre-anesthetic medication and preparation :** A thorough pre-anesthetic evaluation was done to assess the general condition and status of cardiovascular, respiratory, and central nervous system. Routine investigations like hemoglobin, total leukocyte count, differential count, bleeding time, clotting time and chest x-ray were done and checked. A written informed consent was taken.

**Premedication :** All the patients were made to fast for 6 hours for solids and milk and 3 hours for clear fluids. All children were premedicated with midazolam 0.5 mg/kg and atropine 20µg/kg orally 30 minute before surgery. Baseline preoperative values Like heart rate and SpO<sub>2</sub> were recorded. Hemoglobin values were also noted down. All children were pre induced with sevoflurane (5-8vol %) administered via facemask to make the cannulation of peripheral vein more convenient for children and staff. Once intravenous line was accessed sevoflurane was switched off. Patients were randomly allocated into two groups Group A (Propofol) and Group B (Sevoflurane). In propofol -fentanyl group anesthesia was induced with propofol 2mg/kg, fentanyl 2µg/kg and vecuronium 0.1mg/kg. In the same group anesthesia was maintained by with an intravenous bolus dose of fentanyl or vecuronium, and oxygen air mixture without inhalational anesthetics. An intravenous bolus dose of propofol 1-2mg/kg was given every 45 min during surgical procedure. In sevoflurane –fentanyl group anesthesia was induced with sevoflurane (5-8vol%) and maintained sevoflurane (0.8-1 vol%) in oxygen air mixture, supplemented with fentanyl 2µg/kg and vecuronium.

The readings for heart rate and SpO<sub>2</sub> were recorded every 10 minutes during surgery and filled in the proforma prepared. The intra operative complications like difficulty in intubation, cardiac arrhythmias and bronchospasm if occurred was noted down.

**Postoperatively :** After the completion of surgery and resumption of spontaneous respiratory attempt, neostgmine 0.05mg/kg and glycopyrrolate 0.01mg/kg was given to reverse residual neuromuscular blockade. Patients were extubated after adequate muscle power, reflexes and spontaneously respiration. Post operatively heart rate and SpO<sub>2</sub> were recorded every 10 minutes and any complications like emergence agitation and nausea /vomiting were recorded over 2 hours in postoperative ward. Hemoglobin was estimated 6 hours after the surgery. The complications were recorded as (Y = Present ; N = Absent ) . The proforma include the following parameter : Patients Name, IPD. No, Age, sex, Weight, duration of Surgery, Type Of Surgery, duration of anesthesia comparative between to groups. As well as records was having comparative parameter for SpO<sub>2</sub> , Heart rate, Hb during Preoperative/ Intraoperative/Postoperative. The record during intraoperative notes for comparison between propofol

and Sevo group with parameter on Difficulty in Intubation, Vertical extrasystole, Laryngospasm as well as separate complication record. The post

operative comparison between two groups on parameters like emergence agitation, Nausea & vomiting and Extubation stridor were also checked.

**RESULTS**

The comparative results are document in well illustrate tables.

	GROUP	N	Mean	Std. Deviation	t	df	Sig. (2-tailed)
<b>PRE HR</b>	PROPOFOL	37	101.65	13.064	-0.976	75	0.332
	SEVOFLURANE	40	127.75	162.096			
<b>I-HR</b>	PROPOFOL	37	106.35	13.263	1.168	75	0.247
	SEVOFLURANE	40	103	11.916			
<b>PS-HR</b>	PROPOFOL	37	109.19	12.501	-1.257	75	0.213
	SEVOFLURANE	40	112.63	11.491			
<b>PRE-HB</b>	PROPOFOL	37	11.0973	0.842446	-0.921	75	0.36
	SEVOFLURANE	40	11.275	0.849359			
<b>PS-HB</b>	PROPOFOL	37	10.24324	0.766138	0.193	75	0.847
	SEVOFLURANE	40	10.185	1.675701			
<b>PRE-SPO2</b>	PROPOFOL	37	100	.000a			
	SEVOFLURANE	40	100	.000a			
<b>I-SPO2</b>	PROPOFOL	37	99.92	0.277	-0.098	75	0.922
	SEVOFLURANE	40	99.93	0.267			
<b>PS-SPO2</b>	PROPOFOL	37	100	.000a			
	SEVOFLURANE	40	100	.000a			

**TABLE.1: T test for comparison between the Propofol and Sevoflurane groups for each parameters**

GR:			Mean	N	Std. Deviation	Mean	Std. Deviation	t	df	Sig. (2-tailed)
<b>GR:A</b>	Pair 1	PRE-HB	11.0973	37	0.842446	0.854054	0.376825	13.786	36	<b>&lt;0.001</b>
		PS-HB	10.24324	37	0.766138					
	Pair 2	PRE-SPO2	100	37	0	0.081	0.277	1.782	36	0.083
		I-SPO2	99.92	37	0.277					
	Pair 3	I-SPO2	99.92	37	0.277	-0.081	0.277	-1.782	36	0.083
		PS-SPO2	100	37	0					
	Pair 4	PRE-SPO2	100.00a	37	0					
		PS-SPO2	100.00a	37	0					
	Pair 5	PRE HR	101.65	37	13.064	-4.703	6.173	-4.634	36	<b>&lt;0.001</b>
		I-HR	106.35	37	13.263					
	Pair 6	I-HR	106.35	37	13.263	-2.838	6.185	-2.791	36	<b>0.008</b>
		PS-HR	109.19	37	12.501					
	Pair 7	PRE HR	101.65	37	13.064	-7.541	6.172	-7.432	36	<b>&lt;0.001</b>
		PS-HR	109.19	37	12.501					
<b>GR:B</b>	Pair 1	PRE-HB	11.275	40	0.849359	1.09	1.832723	3.761	39	<b>0.001</b>
		PS-HB	10.185	40	1.675701					
	Pair 2	PRE-SPO2	100	40	0	0.075	0.267	1.778	39	0.083
		I-SPO2	99.93	40	0.267					
	Pair 3	I-SPO2	99.93	40	0.267	-0.075	0.267	-1.778	39	0.083

		PS-SPO2	100	40	0					
Pair 4		PRE-SPO2	100.00a	40	0					
		PS-SPO2	100.00a	40	0					
Pair 5		PRE HR	127.75	40	162.096	24.75	160.765	0.974	39	0.336
		I-HR	103	40	11.916					
Pair 6		I-HR	103	40	11.916	-9.625	5.745	-10.595	39	<b>&lt;0.001</b>
		PS-HR	112.63	40	11.491					
Pair 7		PRE HR	127.75	40	162.096	15.125	159.872	0.598	39	0.553
		PS-HR	112.63	40	11.491					
<b>The correlation and t cannot be computed because the standard error of the difference is 0.</b>										

**Table.2: Comparison of the change in the three intervals within the groups: paired t test.**

			GROUP		Total
			Propofol	Sevoflurane	
<b>NAUSEA/VOMITIN G</b>	N	Count	35	28	63
		% within NAUSEA/VOMITIN G	55.6%	44.4%	100.0%
		% within GROUP	94.6%	70.0%	81.8%
	Y	Count	2	12	14
		% within NAUSEA/VOMITIN G	14.3%	85.7%	100.0%
		% within GROUP	5.4%	30.0%	18.2%
<b>Total</b>		Count	37	40	77
		% within NAUSEA/VOMITIN G	48.1%	51.9%	100.0%
		% within GROUP	100.0%	100.0%	100.0%

**Table.3: Nausea/Vomiting Group Cross-tabulation**

			GROUP		Total
			Propofol	Sevoflurane	
<b>EMERGENCE AGITATION</b>	N	Count	34	29	63
		% within EMERGENCE AGITATION	54.0%	46.0%	100.0%
		% within GROUP	91.9%	72.5%	81.8%
	Y	Count	3	11	14
		% within EMERGENCE AGITATION	21.4%	78.6%	100.0%
		% within GROUP	8.1%	27.5%	18.2%
<b>Total</b>		Count	37	40	77
		% within EMERGENCE AGITATION	48.1%	51.9%	100.0%
		% within GROUP	100.0%	100.0%	100.0%

**Table.4: Cross-tabulation for emergence agitation**

**DISCUSSION**

The choice of anesthetic agent mainly depends on preference of anesthesiologist. The ideal i.v induction agent should be stable in aqueous solutions, non irritating, and should produce rapid and smooth onset of hypnosis without cardio-respiratory depression.

It should be eliminated quickly from the brain and have a fast metabolism to non-toxic metabolites. Propofol has become a good choice for induction of anesthesia in pediatrics, although pain, when the drug is injected into small veins, is a problem.

Methohexitone and etomidate have also been employed for brief outpatient anaesthesia, but the smoother induction gives propofol an edge over these drugs<sup>1</sup>. The main advantage with propofol is the smooth and fast recovery. Recovery following induction with propofol is comparable to that of methohexitone, and is faster when compared to thiopentone. A positive 'side effect' with propofol is that it reduces nausea and vomiting<sup>1</sup>. Sevoflurane is more advantageous over halothane as according to Kumar P et al<sup>2</sup> study to compare halothane with sevoflurane inhalation in children for tracheal intubation in children for tracheal intubation. They opined that halothane and sevoflurane provided similar intubating condition but higher success rate with sevoflurane is advantageous because it produces less myocardial depression and propensity to increase the heart rate.

The aim of this study was to determine and compare the intra-operative and post operative complication rates of propofol-based anaesthesia versus sevoflurane-based anaesthesia in pediatric cleft lip, palate and alveolus repair. This study included 77 children aged from 6 months to 12 years undergoing cleft lip palate and alveolus surgery, they were randomly distributed, 40 in sevoflurane group (Group-B) and 37 in propofol group (Group-A). The age, weight and gender distribution in both groups had no significant difference in two groups. Oxygenation was satisfactory (SpO<sub>2</sub> - 99% -100%) throughout the surgery in both the groups. There were no significant difference in heart rate between the two groups; however there were significant changes in preoperative and intra-operative heart rates in both the groups. Hemoglobin pre-operatively and post-operative showed significant drop in both the groups. The emergence agitation and nausea /vomiting was significantly higher in sevoflurane group. Emergence agitation is not specifically related to this type of surgery but it can be associated with usage of sevoflurane. Some investigators argue that emergence agitation occurs as a result of pain due to insufficient analgesia but there is evidence that pain free child with caudal block becomes agitated during emergence from anaesthesia.

In this study emergence agitation occur despite of sufficient intra operative pain control with fentanyl in both groups. There is body of evidence on emergence agitation after use of sevoflurane in children but its cause has not been elucidated there are various school of thoughts for mechanism, it can be because of rapid removal of residual anaesthetics due to low blood solubility of sevoflurane, lack of a young child's ability to adapt to sudden changes due to an unfamiliar environment after awakening, immature neurological development, anxiety from being separated from their parents, increased pain sensation and sympathetic hyper activation. This study result is in concordance with study done by Goto T et al<sup>3</sup> did a study to compare emergence agitation after

sevoflurane versus propofol in pediatric patients. 38% developed emergence agitation. In contrast, none developed emergence agitation when propofol was administered for maintenance of anaesthesia. Parent satisfaction with anaesthesia was greater with propofol than with sevoflurane. Kuratani N et al<sup>4</sup> conducted a meta-analysis of randomized controlled trials to find out greater incidence of emergence agitation in children after sevoflurane anaesthesia as compared with halothane. Kim JH<sup>5</sup> wrote a paper on mechanism of emergence agitation induced by sevoflurane anaesthesia which explained that rapid removal of residual anaesthetics due to low blood solubility of sevoflurane has been suggested to cause emergence agitation in some patients. In addition, a variety of other explanations have been proposed for the etiology of emergence agitation. There have been many attempts to reduce the incidence of emergence agitation but the etiology and preventive treatments of emergence agitation are still unclear.

In our study it was also found that there was significant episodes of nausea and vomiting in sevoflurane group (11 patients) as compared to propofol group (2 patients). There were similar finding in a study done by Jokela RM et al<sup>6</sup> who compared postoperative nausea and vomiting after sevoflurane with or without ondansetron. The incidence of vomiting in the post operative unit did not differ among the three anaesthetic techniques. Compared with either propofol or sevoflurane alone, the combination of sevoflurane and ondansetron resulted in a smaller incidence of PONV during the 24-hour study period. Ferind et al<sup>7</sup> conducted a study to assess the quality of anaesthesia and recovery and the frequency of post anaesthetic retching and vomiting with propofol anaesthesia for pediatric strabismus surgery. He found out that propofol induction and maintenance of anaesthesia for strabismus surgery in children significantly lowers the frequency of post anaesthetic retching and vomiting, but propofol is associated with pain and spontaneous movements at induction and a high frequency of oculocardiac reflexes during maintenance infusion. Thus by our study it was inferred that sevoflurane- fentanyl was more often associated with emergence agitation and nausea vomiting as compared to propofol-fentanyl.

## CONCLUSION

Careful choice of anaesthetic agents reduces the frequency of anaesthesia related complications. Sevoflurane – fentanyl as compared to propofol-fentanyl was associated with more cases of emergence agitation, nausea and vomiting episodes. There were no significant differences in parameters like heart rate and SpO<sub>2</sub> between the two anaesthetic groups in the study. Hemoglobin showed significant drop post operatively. Propofol based anaesthesia in children is safer than sevoflurane –based anaesthesia regarding occurrence of emergence agitation and nausea and vomiting. For time being it is recommended to use

sevoflurane prudently for longer surgical procedures in children and avoidance of sevoflurane for maintenance of anesthesia can reduce the occurrence of emergence agitation without the need of further intervention.

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