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A Comparative Evaluation of Fixed High Concentration Versus Incremental Concentration of Sevoflurane for Induction And Intubation without Muscle Relaxant In Paediatric Patients

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Abstract
Background: *Inhalational anesthesia is the preferred technique of induction in the paediatric age group. Halothane with its negligible pungency and minimal effects on airway reactivity has been the cornerstone of pediatric inhalational induction. Continued research to manufacture an inhalational agent which would match the induction properties of halothane, with minimal cardiac and hepatic side effects and requiring lesser time for induction and emergence led to the introduction of Sevoflurane.*
Materials and Methods*: Sixty patients ASA Grade I and II aged 2-6 yrs were randomly divided into two groups. Group A patients were induced and intubated with 8% Sevoflurane in nitrous oxide and oxygen in a ratio of 2:1 without muscle relaxant. Group B patients were induced and intubated with incremental Sevoflurane in nitrous oxide and oxygen in a ratio of 2:1 with 1% increase every 2-3 breaths without muscle relaxant. In the high concentration group, the anesthesia circuit was primed with 8% sevoflurane in a 2:1 nitrous oxide: oxygen ratio. Patient breathed this gas mixture spontaneously through facemask until loss of eyelash reflex. In the incremental group, face mask was applied and 1% sevoflurane in the same gas ratio was administered. In this group sevoflurane was increased by 1% every 2 to 3 breaths. Induction time was noted and was taken from face mask application to loss of the eyelash reflex (T1). Intubation was attempted when pupils became constricted and centralized, and intubation time was recorded (face mask application to centralization of pupils).*
Results: *Induction time (T1) was taken as the time from face mask application to the loss of eyelash reflex. Mean induction time ± standard deviation observed in Group A was 24.30 ± 9.60 seconds, while in Group B it was 130.93 ± 44.65 seconds. On comparing the two groups using unpaired student's 't' test, the difference between the two groups was found to be statistically highly significant (p value<0.01). T2 (intubation time) was taken as time during which intubation was attempted and was taken from face mask application to when pupils became centralized and constricted. Mean intubation time ± standard deviation observed in Group A was 123.26 ± 18.37 seconds, while in Group B it was 216.26 ± 45.67 seconds. On comparing the two groups using unpaired student's 't' test, the difference between the two groups was found to be statistically highly significant (p<0.01).*
Conclusion: *Sevoflurane use as sole anesthetic agent for induction and intubation is associated with significant changes in heart rate ,blood pressure and oximetric values in both the groups.The induction and intubation time was significantly shorter in high concentration group. Since both the techniques (high concentration & incremental) of sevoflurane was associated with significant changes in haemodynamics and pulse oximetery , hence it is concluded that sevoflurane induction and intubation without use of muscle relaxant is not safe in paediatric age groups.*

Keywords: *Sevoflurane, Inhalational induction.*

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I. Introduction

Inhalational anesthesia is the preferred technique of induction in the paediatric age group. Halothane with its negligible pungency and minimal effects on airway reactivity has been the cornerstone of pediatric inhalational induction despite its propensity to cause bradycardia, hypotension and arrhythmias **(Wodey *et al.*, 1997)**[24]. Continued research to manufacture an inhalational agent which would match the induction properties of halothane, with minimal cardiac and hepatic side effects and requiring lesser time for induction and emergence

led to the introduction of Sevoflurane. Sevoflurane is fluorinated methyl isopropyl ether which is used as a volatile anesthetic agent.

Sevoflurane is a relatively newer inhalational anaesthetic agent & was first synthesized by Regan at Travenol laboratories in 1968, but was introduced in clinical practice in Japan in 1990. When compared to other inhalational agents, it has better properties. Its insoluble nature, low blood gas partition coefficient, no pungency and rapid wash in and rapid wash out makes it an ideal choice for the volatile induction and maintenance of anaesthesia. Its good haemodynamic profile and non irritating nature also adds to its increased acceptance amongst the anaesthesiologists. The vapour pressure of sevoflurane resembles that of halothane and isoflurane permitting delivery of this anesthetic via conventional unheated vaporizer. The fast induction and recovery is due to Blood-gas partition coefficient of 0.69. Compared with isoflurane, recovery from sevoflurane anesthesia is 3-4 minutes faster and difference is magnified in longer duration surgical procedures (>3 hours) **(Ebert *et al.*, 1998)**[8]. Inhalational induction of anesthesia with sevoflurane uses either low or high concentrations of sevoflurane. The low concentration technique involves initially administering a low concentration of sevoflurane, then increasing the concentration until the patient is anaesthetized. The high concentration technique involves administering high concentrations of sevoflurane (from 6 to 8%) from the beginning, continuing until the patient is anesthetized **(Eger II *et al.*, 2003)**[7]. Both techniques can be carried out using different breathing patterns, either vital capacity or tidal volume breathing. The vital capacity method consists of breathing out the residual volume then taking a maximal breath and holding as long as is comfortable followed by spontaneous respiration; and the tidal volume method involves normal breathing and respiratory rate.

II. Aim & Objectives

The aim of our study was to compare and evaluate induction characteristics and intubating conditions with fixed high concentration of sevoflurane versus incremental concentration and to record complications, if an

III. Material & Methods

After written and informed consent from the parents, sixty ASA I and II patients, aged 2-6 yrs of either sex undergoing surgery under general anaesthesia were randomly divided into two groups of 30 each. Patients with ASA III or above, patients with difficult airway, history of malignant hyperthermia, any documented allergy to the study drug, H/O any exposure to halogenated agent with past 6 weeks were excluded from the study.

Group A: Patients were induced and intubated with 8% sevoflurane in nitrous oxide and oxygen in a ratio of 2:1 without muscle relaxant.

Group B: Patients were induced and intubated with incremental sevoflurane in nitrous oxide and oxygen in a **ratio of 2:** 1 with 1% increase every 2-3 breaths without muscle relaxant.

Patients were asked to fast for 6 hours. All patients received injection glycopyrrolate 4µgm/kg intramuscular 45 minutes before surgery. Patients were allocated to one of the study groups by the process of randomization by random table method. After receiving the patient in the operating room, monitors were attached to the patients and all baseline parameters like heart rate, pulse oximetery and blood pressure on the right arm were recorded. In the high concentration group, the anesthesia circuit **(Mapleson-F)** was primed with 8% sevoflurane in a 2:1 nitrous oxide: oxygen ratio. Patient breathed this gas mixture spontaneously through facemask until loss of eyelash reflex. Intravenous line was secured at this point.

In the incremental group, face mask was applied and 1% sevoflurane in the same gas ratio was administered. In this group sevoflurane was increased by 1% every 2 to 3 breaths. Induction time was noted and was taken from face mask application to loss of the eyelash reflex (T1). All vital parameters like heart rate, blood pressure and pulse oximetery were recorded every one minute. Mean arterial pressure was calculated according to formula (SBP+2×DBP)/3. Oxygen saturation was monitored throughout the procedure. Induction complications like bradycardia, cough, laryngospasm, apnea, bronchospasm, hypotension, desaturation, involuntary movements and breath holding were recorded. Fall of mean arterial blood pressure greater than 20% of baseline was taken as hypotension. Any reading of SpO_2 <90% was taken as desaturation. If the end tidal carbon dioxide partial pressure increased over 45 mmHg ventilation was gently manually assisted, targeting an end tidal CO_2 of 32-40 mmHg. Intubation was attempted when pupils became constricted and centralized, and intubation time was recorded (face mask application to centralization of pupils). Quality of intubating conditions were assessed and recorded as per the scoring system devised by **Helbo-Hansen *et al.* (1988)**[13] and later modified by Steyn *et al.* (1994).

S. No.	Laryngoscopy	Vocal cords	Coughing	Jaw relaxation	Limb movement
1.	Easy	Open	None	Complete	None
2.	Fair	Moving	Slight	Slight	Slight
3.	Difficult	Closing	Moderate	Stiff	Moderate
4.	Impossible	Closed	Severe	Rigid	Severe

All variables were allocated score of 1-4 with 1 being ideal condition. Therefore, best possible score was 5. Intubating conditions were considered unacceptable if a score of 3-4 was recorded in any individual category.When the trachea was intubated, anesthesia was maintained with oxygen, nitrous oxide, sevoflurane and supplemented with tramadol in a dose of 0.5 mg/kg. Atracurium was used as muscle relaxant. Patient was monitored after intubation every 3 minutes for next 15 minutes. At the end of surgical procedure the child was reversed with injection neostigmine 0.05 mg/kg and glycopyrrolate. Post extubation child was shifted to recovery room for monitoring vitals.

IV. Observation And Results

There was no statistical difference between the two groups with respect to age, weight, gender and ASA of the patients. Induction time (sec) was faster in Sevoflurane group (48.4±5.04) as compared to Propofol group (60.2±6.53) with a ($p<0.001$), which is highly significant. Also, the intraoperative haemodynamic parameters consisting of heart rate and blood pressure were comparable between the two groups with no statistically significant difference.

Table 6 : Comparative evaluation of mean values of pre-intubation vitals at 0 minute

Parameters	Group A (Mean ± SD) (N = 30)	Group B (Mean ± SD) (N = 30)	Statistical Inference	
			't' value	'p' value
Mean heart rate (per min)	109.26 ± 9.9	104.07 ± 10.74	1.94	0.05*
Mean systolic blood pressure (mmHg)	113.76 ± 13.37	119.23 ± 11.92	1.6	0.10*
Mean diastolic blood pressure (mmHg)	68.93 ± 10.64	73.33 ± 9.54	1.67	0.09*
Mean arterial blood pressure (mmHg)	83.87 ± 10.91	88.63 ± 9.46	1.80	0.07*
Mean oxygen saturation (%)	99.00 ± 0.58	98.80 ± 0.48	1.43	0.15*

*Non-significant

Table 7 : Comparative evaluation of mean values of pre-intubation vitals at 1 minute

Parameters	Group A (Mean ± SD) (N = 30)	Group B (Mean ± SD) (N = 30)	Statistical Inference	
			't' value	'p' value
Mean heart rate (per min)	111 ± 11	105 ± 14	1.95	0.05*
Mean systolic blood pressure (mmHg)	108.06 ± 10.77	112.46 ± 8.9	1.72	0.09*
Mean diastolic blood pressure (mmHg)	65.76 ± 9.98	68.63 ± 8.9	1.17	0.24*
Mean arterial blood pressure (mmHg)	79.86 ± 9.71	83.24 ± 8.47	1.43	0.15*
Mean Oxygen saturation (%)	99.23 ± 0.62	99.26 ± 0.73	0.18	0.85*

*Non-significant

Table 9 : Comparative evaluation of mean values of pre-intubation vitals at 3 minutes

Parameters	Group A (Mean ± SD) (N = 30)	Group B (Mean ± SD) (N = 30)	Statistical Inference	
			t' value	'p' value
Mean heart rate (per min)	115.90 ± 9.24	112.66 ± 12.00	.16	0.24*
Mean systolic blood pressure (mmHg)	111.40 ± 8.66	113.86 ± 7.98	.47	0.25*
Mean diastolic blood pressure (mmHg)	61.33 ± 9.8	63.53 ± 8.76	.92	0.36*
Mean arterial blood	78.02 ± 8.75	80.31 ± 7.52		0.28*

pressure (mmHg)			.08	
Mean Oxygen saturation (%)	99.70 ± 0.53	99.53 ± 0.62	.10	0.27*

*Non-significant

Table 10 : Comparative evaluation of mean values of post-intubation vitals at 0 minute

Parameters	**Group A (Mean ± SD) (N = 30)**	**Group B (Mean ± SD) (N = 30)**	**Statistical Inference**	
			't' value	'p' value
Mean heart rate (per min)	109.58 ± 7.68	107.03 ± 10.72	1.04	0.30*
Mean systolic blood pressure (mmHg)	112.33 ± 7.45	113.56 ± 5.85	0.71	0.48*
Mean diastolic blood pressure (mmHg)	60.00 ± 8.22	60.40 ± 7.47	0.19	0.84*
Mean arterial blood pressure (mmHg)	78.54 ± 7.57	78.12 ± 5.64	0.25	0.81*
Mean Oxygen saturation (%)	99.66 ± 0.54	99.56 ± 0.62	0.65	0.51*

*Non-significant

Table 11 : Comparative evaluation of mean values of post-intubation vitals at 3 minutes

Parameters	**Group A (Mean ± SD) (N = 30)**	**Group B (Mean ± SD) (N = 30)**	**Statistical Inference**	
			t' value	'p' value
Mean heart rate (per min)	107.26 ± 8.9	101.83 ± 13.14	.87	0.06*
Mean systolic blood pressure (mmHg)	114.16 ± 7.38	113.06 ± 6.49	.61	0.54*
Mean diastolic blood pressure (mmHg)	58.20 ± 5.28	58.40 ± 5.74	.14	0.88*
Mean arterial blood pressure (mmHg)	76.85 ± 4.90	76.62 ± 4.70	.18	0.85*
Mean Oxygen saturation (%)	99.16 ± 0.79	99.10 ± 0.96	.29	0.77*

*Non-significant

Table 12 : Comparative evaluation of mean values of post-intubation vitals at 6 minutes

Parameters	**Group A (Mean ± SD) (N = 30)**	**Group B (Mean ± SD) (N = 30)**	**Statistical Inference**	
			't' value	'p' value
Mean heart rate (per min)	104.2 ± 9.5	98.80 ± 12.22	1.91	0.06*
Mean systolic blood pressure (mmHg)	112.10 ± 3.90	111.34 ± 5.94	0.58	0.56*
Mean diastolic blood pressure (mmHg)	59.43 ± 7.03	57.66 ± 4.08	1.19	0.24*
Mean arterial blood pressure (mmHg)	76.98 ± 5.47	74.32 ± 7.27	1.60	0.11*
Mean Oxygen saturation (%)	99.46 ± 0.62	99.33 ± 0.66	0.80	0.42*

*Non-significant

Table 21 : Comparative evaluation of mean values of induction time (in seconds) in two groups

Parameters	**Group A (Mean ± SD) (N = 30)**	**Group B (Mean ± SD) (N = 30)**	**Statistical Inference**	
			't' value	'p' value
Induction time (in seconds)	24.30 ± 9.60	130.93 ± 44.65	12.78	0.00**

**Significant

T1 was taken as induction time from face mask application to the loss of eyelash reflex. Mean induction time ± standard deviation observed in Group A was 24.30 ± 9.60 seconds, while in Group B it was 130.93 ± 44.65 seconds. On comparing the two groups using unpaired student's 't' test, the difference between the two groups was found to be statistically highly significant (p value<0.01).

Comparative evaluation of mean values of intubation time (in seconds)

Parameters	**Group A (Mean ± SD) (N = 30)**	**Group B (Mean ± SD) (N = 30)**	**Statistical Inference**	
			't' value	'p' value
Intubation time (in seconds)	123.26 ± 18.37	216.26 ± 45.67	10.34	0.00**

**Significant

T2 (intubation time) was taken as time during which intubation was attempted and was taken from face mask application to when pupils became centralized and constricted. Mean intubation time ± standard deviation observed in Group A was 123.26 ± 18.37 seconds, while in Group B it was 216.26 ± 45.67 seconds. On comparing the two groups using unpaired student's 't' test, the difference between the two groups was found to be statistically highly significant (p<0.01).

Comparative evaluation of complications observed in patients of two groups

Complications	**Group A N = 30 No. (%)**	**Group B (N = 30) No. (%)**
Arrthythmias	–	–
Apnea	4 (13.33)	–
Desaturation	–	–
Bronchospasm	–	–
Bradycardia	–	–
Hypotension	–	–
Laryngospasm	–	–
Cough	–	2 (6.67)
Breath holding	–	4 (13.33)

Chi-square = 0.48; p = 0.48 (Non-significant)

The above table depicts that Group A had 4 (13.33%) cases of apnea which were managed by positive pressure ventilation. Two (6.67%) patients in Group B had slight coughing and 4 (13.33%) patients had breath holding. When evaluated comparatively, complications were found to be non-significant (p=0.48).

Table 24 : Intergroup comparison of Steyn's modification of Helbo-Hansen intubating condition scoring system

Parameters	**Group A (Mean ± SD) (N = 30) No. (%)**	**Group B (Mean ± SD) (N = 30) No. (%)**	**Statistical Inference (Fisher's exact test)**
Laryngoscopy			
Easy	**30 (100.00)**	**30 (100.00)**	**p = 1 (non-significant)**
Vocal cords			
Open	**30 (100.00)**	**27 (90.00)**	**p = 0.23 (non-significant)**
Moving	**–**	**3 (10.00)**	
Coughing			
None	**30 (100.00)**	**28 (93.33)**	**p = 0.49 (non-significant)**
Slight	**–**	**2 (6.67)**	
Jaw relaxation			
Complete	**30 (100.00)**	**30 (100.00)**	**p = 1 (non-significant)**
Limb movements			
None	**30 (100.00)**	**29 (96.67)**	**p = 1 (non-significant)**
Slight	**–**	**1 (3.33)**	

The above table shows that all 100% patients in both Group-A and Group B had easy laryngoscopy and complete jaw relaxation. In Group-B, 3 (10%) patients had moving vocal cords, 2 (6.67%) patients had slight coughing and 1 (3.37%) patient had slight limb movement. Using Fisher's exact test, the difference between the parameters of Helbo-Hansen Intubating Condition Scoring System were found to be statistically non-significant in the two groups (p-value>0.05).

V. Discussion

General anesthesia (GA) may be induced either by intravenous injection (IV induction) or by breathing in a volatile anesthetic agent along with oxygen through a mask (inhalational induction).Inhalational anesthetic induction may be the preferred method in children and in some adult patients who refuse intravenous cannulation or have poor venous access **(Eger II *et al.,* 2003)**[7] One of the commonly used volatile anaesthetic agents for inhalational induction of anaesthesia is sevoflurane (Ulthane™, Sevorane™). Its characteristics are inherent stability, low flammability, non-pungent odour, limited irritation to airways, low blood or gas anaesthetic solubility, which allows rapid induction and emergence from anesthesia and minimal cardiovascular and respiratory side effects and minimal end-organ effects **(Delgado-Herrera *et al.,* 2001)**[5]. Sevoflurane's muscle relaxation properties allow the insertion of a laryngeal mask airway (LMA) or endotracheal intubation without a muscle relaxant **(Aantaa *et al.,* 2001)**[1].

In our study, children of Group A were induced and intubated with 8% sevoflurane in nitrous oxide and oxygen in a ratio of 2:1 without muscle relaxant and Group B were induced and intubated with incremental sevoflurane in nitrous oxide and oxygen in a ratio of 2:1 with 1% increase every 2-3 breaths without muscle relaxant. Nitrous oxide was used as it has 20-25% MAC reducing properties for sevoflurane **(Katoh *et al.,* 1992)**[14] and decreases adverse airway events and excitatory phase as seen by **Hall *et al.* (1997)**[12].

During induction period, mean heart rate increased in both groups but it was more in Group B as compared to Group A (7% versus 5.7%) but was statistically non-significant. **Thwaites *et al.* (1997)**[21]**, Dubois *et al.* (1999)**[6] **and Kudalkar (2004)** all found similar increase in heart rate in both the groups. However, **Green *et al.* (2000)**[11] reported drop in heart rate. In his study, pediatric patients were unpremedicated and were of younger age group (<1 year), who had immature autonomic nervous system, making them more susceptible to bradycardia. However, in our study, no case of bradycardia was seen as we had used anticholinergic drug as premedication. In our study, all patients remained hemodynamically stable in both the groups during induction period with no episode of desaturation. In other studies too (**O'Brien *et al.,* 1998**[16]**; Epstein *et al.,* 1998**[9]**)**, similar observations were made. But there are studies which have reported fall in blood pressure during induction **(Sabapathy *et al.,* 2011)**[19]. This could be because they used midazolam and fentanyl before induction

Mean post-intubation vitals like heart rate, blood pressure and pulse oximetery values at interval of 0, 3 and 6 minutes in both groups remained statistically non-significant ($p>0.05$). In our study, in both the groups, patients remained haemodynamicaly stable during induction and post-intubation with no episode of hypotension, bradycardia, tachycardia and desaturation and these results were statistically non-significant. Similar findings were reported by **O'Brien *et al.* (1998)**[16] and **Wappler *et al.* (2003)**[23]. **Sabapathy *et al.* (2011)**[19] found significant drop in blood pressure post-intubation, and this could be because they used midazolam and fentanyl before induction.

In our study, there was highly significant difference ($p<0.01$) in induction time in Group A having 24.30±9.60 seconds and Group B with mean induction time of 130.93± 44.65 seconds. The results are similar to those of **Baum *et al.* (1997)**[3]**, Epstein *et al.* (1998)**[9] **& Abdel-Halim *et al.* (2002)**[2]In contrast to above results, **Sigston *et al.* (1997)**[20] induced children with 8% sevoflurane in 66% nitrous oxide and oxygen and noted that induction time with sevoflurane was 82±18 seconds. Although, induction time was higher in their study but overpressure facemask technique was not applied in their patients as we did it in our study. This could be the reason for short induction time in our study.**Redhu *et al.* (2010)**[18] induced children in age group of 6 months to 6 years and found that induction time with incremental sevoflurane was 77.06±13.06 seconds. In their study, children were premedicated with midazolam 0.1 mg/kg intravenously, and as we know benzodiazepines are known to reduce the MAC of inhaled anesthetics, this could be the reason for short induction time in their study.

Similarly there was highly significant difference ($p<0.01$) in mean intubation time in both the groups, with Group A having 123.26±18.37 seconds and Group B with 216.26±45.67 seconds. Similar results were reported by **O'Brien *et al.* (1998)**[16] and **Redhu *et al.* (2010)**[18].All patients had acceptable intubating conditions in both groups. All patients in both groups had easy laryngoscopy with best possible **Helbo-Hansen** score of one. All patients had complete jaw relaxation in both groups with best possible Helbo-Hansen of score one. All patients in Group A had open vocal cords but 3 (10%) patients in Group B had moving vocal cords with Helbo-Hansen score of 2. All patients in Group A had no coughing but 2 (6.67%) patients in Group B had slight coughing with Helbo-Hansen score of 2. Only 1 patient (3.33%) in Group B had slight limb movements. However, these results were statistically not significant ($p>0.05$).

In terms of complications, fixed high concentration group (Group A) had four (13.33%) cases of apnea which were managed by positive pressure ventilation but they were also of transient nature as patients were breathing spontaneously after some time and this is supported by the study of **Pancaro (2005)**, who observed that incidence of apnea is high and of longer duration when sevoflurane is administered in high concentration. Two (6.67%) patients in incremental group (Group B) had slight coughing and four (13.33%) patients had

breath holding. These complications were also non-significant (p>0.05). Sevoflurane was not found to be associated with increased incidence of coughing, laryngospasm, bronchospasm, excessive secretions, vomiting or oxygen desaturation to less than 90% as reported in studies done by **Fredman *et al.* (1995)** and **Smith *et al.* (1995)**.

Baum *et al.* (1997)[3] and **Epstein *et al.* (1998)**[9] also reported very few complications in their study while evaluating high dose sevoflurane and incremental sevoflurane in 70% nitrous oxide. High concentration volatile anesthetic induction has been reported to result in a shorter induction time (**Epstein *et al.*, 1998**[9]**; Martin-Larrauri *et al.*, 2004**[15]) but this may be accompanied by a number of complications such as breath holding, laryngospasm as reported by **Dubois (1999)**[6]. Children in his study group underwent tonsillectomy more frequently. Longer duration of apnea in high concentration group was reported by **Pancaro (2005)**[17]. **Green *et al.* (2000)**[11] studied children who were unpremedicated and of younger age group and found bradycardia in them.

VI. Conclusion

The above observations are summarized as follows.

1. Both groups were comparable in age, sex and weight distribution and there was statistically no significant difference between them.
2. sevoflurane use as sole anesthetic agent for induction and intubation is associated with significant changes in heart rate ,blood pressure and oximetric values in both the groups.
3. The induction and intubation time was significantly shorter in high concentration group.
4. Helbo-Hansen score was acceptable in both the groups and the difference between them was non-significant.
5. Complications occurred with similar frequency in both groups and were statistically non-significant.

Since both the techniques (high concentration & incremental) of sevoflurane was associated with significant changes in haemodynamics and pulse oximetery , hence it is concluded that sevoflurane induction and intubation without use of muscle relaxant is not safe in paediatric age groups.

Conflicts Of Intrest

There are no conflicts of interest.

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