

A COMPARATIVE STUDY OF SEVOFLURANE VS HALOTHANE FOR GENERAL ANAESTHESIA IN PEDIATRIC PATIENTS

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CONTEXT (BACKGROUND): Halothane has been the induction agent of choice in pediatric age group for nearly five decades. Sevoflurane with low blood gas solubility allows rapid induction and early emergence, its pleasant odour makes it an attractive alternative for inhalational induction in children. **AIMS:** Comparison of halothane and sevoflurane regarding induction in children, hemodynamic and respiratory study between two agents, emergence, recovery and side effects. This study was carried out over a period of two years from Dec 2009 to Dec 2011. **SETTINGS AND DESIGN:** Sixty patients were included and analyzed at our hospital after ethical approval. **METHODS AND MATERIAL:** Patients in Group I(n=30) received Halothane while Group-II(n=30) patients received Sevoflurane for induction and maintenance. Parameters recorded and analyzed were Time to loss of eyelash reflex, Time to complete induction, Hemodynamic parameters during induction and at regular intervals, Emergence time and Recovery profile at the end of surgery. **STATISTICAL ANALYSIS USED:** For the purpose of evaluating the results of the study following statistical tools were used: Mean, S.D., t Test, Confidence Level and Chi-square Test. **ANOVA** was used to compare observations taken under different conditions within the same group. **RESULTS:** Time to loss of eyelash reflex and time to complete induction were statistically significant in sevoflurane (Group II) group. A statistically significant difference was seen between two groups with Group I showing significantly higher proportion of complications as compared to Group II (p=0.009). **CONCLUSIONS:** Sevoflurane is a better inhalational agent than halothane because of faster induction and rapid recovery. Hemodynamic stability was better, with less incidence of complications than halothane.

KEY-WORDS: Sevoflurane, Emergence, Recovery, Halothane.

KEY MESSAGES: Sevoflurane anesthesia proved safe, effective and satisfactory for the conduct of wide variety of cases in pediatric age group when compared to Halothane.

INTRODUCTION: General anaesthesia causes central nervous system depression which includes a state of unconsciousness with dose dependent depression of physiological functions such as respiratory, neurological, cardiovascular, renal, hepatic and muscular system.

The induction of sleep by inhalation has a tradition in anaesthesia, which encompasses our very roots. Many attribute the beginning of modern anaesthesia to Morton's demonstration of the inhalation of ether in the mid nineteenth century. Almost immediately, the search began for a safe agent, which facilitated inhalation induction, as ether too often produce a prolonged, unpleasant and stormy induction.

Introduction of halothane have revolutionized the anaesthetic practice in general and pediatric in particular. Halothane with its negligible pungency and minimum effects on airway reactivity has been the cornerstone of pediatric inhalational induction despite its propensity to cause bradycardia, hypotension and arrhythmias.

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Continued search for an ideal 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 lead to the introduction of several compounds as isoflurane, enflurane, or desflurane have not solved either the comfort or safety of inhalation induction of anaesthesia. Airway complications (coughing, breath-holding, and laryngospasm) do occur more frequently with these than they do with halothane.

Sevoflurane may be an attractive alternative to halothane in outpatient surgery because of lesser myocardial sensitization to catecholamines and low blood gas solubility, when compared with halothane (0.65 versus 2.5);thence associated with more rapid induction of and recovery from anaesthesia. However emergence delirium, production of compound A^{1, 2, 3}, etc are some of the feared disadvantages of Sevoflurane use.

The Pediatric Anaesthesiologists usually prefer anaesthetic techniques associated with a rapid and smooth induction and emergence, early feeding and smooth uneventful postoperative recovery. Many pediatric patients are not premedicated and may arrive in operating room anxious and crying, usually having elevated serum catecholamine levels;thence more liable to develop cardiac dysrhythmias with halothane anaesthesia. Sevoflurane with low blood gas solubility allows rapid induction and early emergence, pleasant odor; being nonirritant to the airway, makes it an attractive alternative for inhalational induction in children.

The current study was conducted to compare halothane and sevoflurane for:

1. Induction of children.
2. Hemodynamic and respiratory study between two agents.
3. Emergence and recovery.
4. Any side effects or complications

SUBJECTS AND METHODS: In a prospective randomized controlled study, 60 patients in age group of one to twelve years, belonging to ASA grade I undergoing elective surgery under general anaesthesia were analyzed at Lucknow from Dec 2009 to Dec 2011.

The procedures followed were in accordance with the ethical standards on human experimentation and the study was approved by the ethics committee of our hospital. The parents or guardians of all the patients were explained and written informed consent was taken. The older children were also briefed about the procedure.

RANDOMIZATION: Computer generated randomization was followed and blinding was done .

INCLUSION CRITERIA

1. Children aged between 1-12 years
2. ASA-1 physical status
Scheduled for elective surgery under general anaesthesia

EXCLUSION CRITERIA

1. Refusal to give consent.
2. Patients for whom inhalation induction was contraindicated.
3. Prior history of halothane exposure/administration.
4. History or family history of malignant hyperthermia.
5. ASA physical status-II or higher were excluded.

6. Patients having history of convulsions, meningitis, infections, anemia (Hb% <9 gm/dl) or any congenital heart disease.
7. Patients having hepatic, renal or neuromuscular disease.
8. Patients having respiratory system disease.
9. Any other contraindication to the drugs used or any drug allergy.

Group Division: All patients were divided in to two groups, according to anaesthetic agent used as following.

Group-I: Patients receiving Halothane using Tec 5 for induction and maintenance along with Nitrous Oxide and Oxygen.

Group-II: Patients receiving Sevoflurane using Tec 7 for induction and maintenance along with Nitrous Oxide and Oxygen.

Preanesthetic Checkup: Each child was selected after a thorough pre-anaesthetic check-up and were investigated for routine investigations. Six hours preoperative fasting for solids and four hours for clear fluids was done in all patients as preparation of general anaesthesia.

Anaesthetic Technique: All the patients were monitored (Datex Ohmeda S/5) for heart rate, blood pressure, respiratory rate, End tidal carbon dioxide, SpO₂, ECG changes before induction, at full induction, 5 minutes, 30 minutes, 60 minutes and 90 minutes after induction, just after and 30 minutes after extubation.

An intravenous line was started in the preoperative area after application of EMLA cream about 45 mnutes before taking into operative area. After shifting the patient to operation theatre and attaching all the monitors, injection Glycopyrrolate 0.005 mg/kg, Injection Ondansetron 0.1 mg/kg, and injection Fentanyl 2 µg/kg body weight were injected.

Thereafter, Induction of anaesthesia was commenced by face mask applied at the end of spontaneous expiration using Jackson-Rees circuit^{4, 5} or non-rebreathing circuit as per the weight of the patient, using 50% Oxygen and 50% Nitrous Oxide (5 L/min each) and incremental concentration of volatile anesthetic agent under study after priming the circuit and appropriately sized pediatric mask. The circuit was primed by emptying anaesthesia bag and refilling it twice. Spontaneous ventilation was maintained until loss of eyelash reflex occurred. Inhalational anaesthesia via mask was continued using assisted ventilation.

In group I the inspired concentration of Halothane was set at 0.5% initially, followed by increase of 0.5% every 3-4 breaths to a maximum of 2%. In Group II, Sevoflurane was set at 1% initially and increased by 1% to a maximum of 5%.

Injection Succinylcholine 2mg/kg was injected after centralization of eyeball and anaesthetic concentration reduced to 0.75% Halothane or 2% Sevoflurane for 60 seconds. Then orotracheal intubation was performed with an appropriate sized endotracheal tube and a pack was placed inside to seal oropharynx. Any complications were noted and treated immediately. Ventilation was controlled to maintain normocapnia with N₂O and O₂ 60% and 40% with total gas flow 2 L/min with closed circle system. Injection Atracurium 0.5 mg/kg injected after patient showed recovery from Succinylcholine, and thereafter 0.1 mg/kg as required throughout surgery.

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The anaesthesia was maintained at 0.2% to 0.6% Halothane or 1% to 1.5% Sevoflurane according to patient response until the end of surgery. At the end of surgery all anaesthetic drugs were discontinued and ventilation was continued with 100% Oxygen at 5 L/min.

With the onset of respiratory attempts and body movements, relaxant was reversed with Neostigmine 0.05 mg/kg and injection Glycopyrrolate 0.01 mg/kg body weight.

Parameters recorded and analyzed were:

- 1- Time to loss of eyelash reflex.
 - 2- Time to complete induction (time of centralization of eyeball).
 - 3- Cardiorespiratory parameters during induction and at regular intervals
- HR=Heart Rate/ SBP=Systolic Blood Pressure/ DBP=Diastolic Blood Pressure/ EtCO₂=End Tidal Carbon dioxide/ RR= Respiratory rate/ SpO₂= Arterial Oxygen Saturation/ECG=Electrocardiography
- 4- Emergence time.
 - 5- Duration of surgery.
 - 6- Recovery profile at the end of surgery by assessing
- Eye opening / Purposeful movements(hand grip) / Cough and gag reflex
- Emergence time was defined as the time from discontinuation of anesthetics to extubation. Time between intubation and extubation was taken as anaesthesia time.

Patients were followed up post operatively for 30 minutes. Any side effects or complications were recorded. Patients were shifted to ward after normalization of all vitals and oxygen saturation. Post operative pain was managed by injection Paracetamol (20mg/kg BW) 6 hourly and titrated thereafter.

Statistical Analysis: For the purpose of evaluating the results of the study following statistical tools were used:

Mean: Means were calculated for all the parametric quantitative data in the study. Mean is an arithmetic average depicting the central tendency of the group.

Standard deviation: Within group variances were evaluated with the help of standard deviation. A higher standard deviation shows the lower reliability of central tendency i.e. mean, while lower standard deviation shows higher reliability of central tendency.

't' Test for independent Samples: To compare the difference in mean values of two groups, 't' test for independent samples was used.

Confidence Level: The confidence level of the study was set at 5%. Hence a "p" value <0.05 depicts a statistically significant difference.

Chi-square Test: To evaluate the significance of difference in proportion between the two groups, chi-square test was used.

ANOVA was used to compare observations taken under different conditions within the same group.

RESULTS: The results were comparable with respect to age, sex, weight, duration and type of surgery. There was no significant statistical difference between heart rate of the two groups ($p>0.05$), however the children in halothane group showed more incidence of bradycardia.

Statistically, no significant difference in Systolic, Diastolic and mean blood pressure was seen at any time interval ($p>0.05$) between two groups.

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In our study, most common surgical procedure was cleft lip repair constituting 61.7% (37 patients) followed by cleft palate repair which constituted 28.3% (17 patients) of all (Table-1 and Fig 1).

Oxygen saturation, ECG and EtCO₂ in two groups were comparable without any statistically significant difference ($p>0.05$).

Time to loss of eyelash reflex and time to complete induction was considerably lesser both clinically and statistically in sevoflurane group. ($p<0.001$). Emergence from anesthesia ($p<0.001$) was significantly faster in patients receiving sevoflurane than in halothane. (Fig. 2). Table 4 depicts the same.

On induction, statistically significant difference was seen between two groups with Group I showing significantly higher proportion of complications as compared to Group II ($p=0.009$). Dysrhythmia was statistically significant in Group I (Halothane) ($p=0.038$, $\chi^2=6.789$). (Fig. 3).

On emergence and recovery, Group II showed higher complications as compared to Group I ($p=0.013$, $\chi^2=6.119$) which were not statistically significant except for excitement ($p=0.001$, $\chi^2=10.417$) being reflected higher in Group II as compared to Group I. (Table 2).

With respect to post operative complications, statistically no significant differences were seen between the two groups except shivering being significantly higher in Group I (26.7%) as compared to Group II (zero), ($p=0.002$, $\chi^2=9.231$). (Table 3).

DISCUSSION: In the present study, we compared hemodynamic, respiratory, induction and recovery characteristics of sevoflurane and halothane in sixty patients of 1-12 years of age undergoing various surgical procedures under general anaesthesia. They were randomized in two groups of 30 patients each according to inhalational agent chosen.

Majority of the patients were 1-6 years age group, constituting 75% (45 patients) of the total patient pool, while 7-12 years of age group patient constituted 25% (15 patients) of all.

In our study, majority of patients were in 10-20 kg group, constituting 50% (30 patients) of the total patient pool, while 0-10 kg group constituted 32.35% (22 patients) and 20-30 kg group constituted remaining 13.33% (8 patients) of all.

Shortest procedure was of 40 minute duration while longest procedure was 127 minutes duration.

In our study, baseline value of mean heart rate per minute recorded before premedication was used as a control group for statistical evaluation. We found that before premedication mean heart rate was not statistically significant difference between the two groups. At full induction, there was more fall in heart rate in group I than in group II. No significant statistical difference was seen between the two groups ($p>0.05$), however the children in halothane group showed more incidence of bradycardia.

There was a fall in Blood Pressure at full induction which was more marked in halothane group than in sevoflurane group. Intraoperatively blood pressure was comparable in both the groups and remained stable throughout and below baseline. Blood pressure increased at extubation and after 30 minutes approached to near baseline. Hypotension (decrease of mean arterial pressure of $>20\%$ from baseline) during induction was seen in 20% of group I and 10% of group II. Statistically, no significant difference in systolic, diastolic and mean blood pressure were seen at any time interval.

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Eger, Smith and Stoelting et al also noted depression of cardiac output, stroke volume, arterial pressure, left ventricular minute and stroke work and myocardial contractility, muscle blood flow and total body oxygen during halothane anaesthesia ⁶.

Statistically no significant differences were seen between the two groups except at the time of full induction when there were 4 cases with dysrhythmia in Group I as compared to none in Group II (p=0.038). One patient manifested dysrhythmia postoperatively in group I and none in group II. All the dysrhythmia corrected by themselves within minutes without requiring any treatment.

Green, Townsend and Bagshaw et al in 2000 compared incremental and high concentration techniques with sevoflurane to assess nodal rhythm and bradycardia during inhalation induction in infants⁷. They found that the use of incremental or high-concentration sevoflurane for anesthetic induction in unpremedicated infants was associated with a 20% incidence of nodal rhythm. This unexpected finding highlights the importance of using continuous ECG analysis when studying the side effects of volatile agents in young children.

Induction and recovery times were shorter with sevoflurane as compared to halothane which were statistically significant.

Abdel-Halim et al. in their study observed that the loss of eyelash reflex with loss of consciousness was significantly more rapid with sevoflurane than with halothane, but the difference in induction times was not significant ⁸.

Villani, Zuccoli and Rovella et al.⁹ did a prospective, randomized clinical comparison of sevoflurane and halothane in children and found that sevoflurane is as effective as halothane in providing smooth and rapid induction of anaesthesia, while recovery is considerably faster and hemodynamic tolerance is better if compared to halothane; this suggests that sevoflurane could be an useful substitute for halothane in pediatric patients ⁹.

Ariffin et al. in their study found that despite more rapid induction of anaesthesia with sevoflurane, the time to awaken was faster with halothane but we found faster induction as well as recovery with sevoflurane ¹⁰

We found similar results as observed by Meena et al., who found faster induction and recovery times with sevoflurane than halothane. They also observed higher incidence of post-operative restlessness and agitation with sevoflurane.¹¹

The present study is in conformity with Dedhia et al. who found in their study that at the time of full induction there was a significant fall seen in the mean systolic pressure in both the groups, but fall was more in halothane group than in sevoflurane group ¹². Hence they concluded that sevoflurane has a rapid induction with better hemodynamic stability and is a better alternative to halothane for inhalation induction of anaesthesia in children.

Politis, Frankland, and James et al found minimal negative hemodynamic effect during sevoflurane inductions in their study ¹³.

With regards to induction characteristics, hiccough was seen in 1 patient in halothane group and 2 patients in sevoflurane group. Salivation occurred in 1 patient in halothane group and none in sevoflurane group. 4 patients of group I and, 2 patients of group II manifested desaturation (SaO₂ <4% from baseline SaO₂) at full induction, however there were no episode of severe arterial desaturation (SaO₂ <85%) reflecting hypoxemia (arterial oxygen tension < 50 mm Hg) at any time of surgery in either of the study group¹⁴. Coughing, laryngospasm and bradypnea during induction were seen in 3, 2 and 3 patients respectively in halothane group while no such complications were

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recorded in sevoflurane group. Breath holding was noted in 5 out of 30 patient in halothane group and 7 out of 30 in sevoflurane group which was statistically not significant. Bradycardia was seen in 10 patients (33.3%) in halothane group and 6 Patients (20%) in sevoflurane group showing no statistical difference.

The only statistically significant difference was the occurrence of dysrhythmia ($p=0.038$), 4 out of 30 in halothane group (13.34%) and none in sevoflurane group. However, on overall comparison, a statistically significant difference was seen between two groups with Group I showing significantly higher proportion of complications as compared to Group II ($p=0.009$).

During emergence sevoflurane group showed more complications which were of minor clinical importance except for excitement which was reasonably more both clinically and statistically (11 out of 30 patients)(36.67%).

Cravero J et al designed a study to compare the emergence characteristics of sevoflurane with halothane anaesthesia in paediatric patients having no surgical intervention and concluded that there is an increased incidence of emergence agitation with sevoflurane anaesthesia compared to halothane independent of any painful stimulus ¹⁵.

The most frequently reported disadvantage of sevoflurane and nitrous oxide anaesthetic is the experience of emergence delirium in the early recovery period. Postoperative agitation has been reduced with the use of certain premedication (midazolam, clonidine) and improved analgesic regimen in some studies.¹⁶⁻²⁰

Robinson et al. observed differences between sevoflurane and isoflurane or propofol anaesthesia, support the postulate that the use of sevoflurane is associated with a more rapid recovery from anaesthesia than either isoflurane or propofol ²¹. We also noticed rapid recovery with sevoflurane.

Jellish et al found in their study that sevoflurane compares favorably with propofol for both ease of induction and emergence from anaesthesia. Sevoflurane may be a useful alternative to propofol in providing anaesthesia where rapid emergence and recovery of cognitive function are desired ²².

Naito et al noted in their study that there was no serious complication associated with the inhalation of sevoflurane ²³.

We found nausea in 10% of sevoflurane group and none in halothane group while vomiting was seen in 6.7% in halothane group and 20% in sevoflurane group.

Yang et al. demonstrated no difference in PONV, pain, or anaesthetic/recovery times or costs between the sevoflurane and propofol groups ²⁴.

Simurina et al in their study concluded that, it is better to avoid inhalational anaesthesia in patients which are usually high risk for postoperative vomiting ²⁵.

We observed that shivering is significantly more in halothane group both clinically and statistically while nausea and vomiting are more in sevoflurane group clinically but not statistically. Hypothermia and dysrhythmia occurred in 1 patient each in halothane group and none in sevoflurane group. Our results are in line with the work of Kiran et al. who observed that sevoflurane anaesthesia is a better alternative for induction in infants undergoing cardiac surgery as compared to isoflurane and halothane

The limitation of our study design is small sample size. A larger number of patients need to be incorporated into study to re-emphasize our results.

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Sevoflurane may be specifically indicated in procedures that can be performed with a spontaneously breathing technique, Short procedures associated with little post-operative pain, Individuals where difficult intubation or ventilation are anticipated, Procedures where rapid emergence is particularly desirable in terms of more rapid awakening and ability to obey commands in longer cases.

After statistical evaluation it was concluded that:

1. Demographic parameters were comparable in the two groups. Most of the surgical procedures were of 1-2 hours duration.
2. Almost all patients in both age groups were hemodynamically stable through out the period of observation.
3. Statistically significant short induction time was found in sevoflurane group of patients.
4. We found better induction characteristics with sevoflurane group than with halothane. Intubating conditions were slightly better in sevoflurane group children as compared to halothane group.
5. Recovery time was statistically significantly shorter in sevoflurane group of patients.
6. Recovery characteristics were significantly better with sevoflurane than with halothane.
7. Postoperative complications were very few and almost similar in both groups.

To conclude, sevoflurane is a better inhalational agent than halothane due to its better induction characteristics and rapid recovery. Hemodynamic stability was also better and incidence of complications were lesser and less worrisome than halothane. Sevoflurane anesthesia proved safe, effective and satisfactory for the conduct of wide variety of cases in clinical practice particularly in pediatric age group.

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Procedure	Group I (Halothane)		Group II (Sevoflurane)		Total	
	No.	%	No.	%	No.	%
Cleft lip repair	18	60	19	63.3	37	61.7
Contracture Release	0	0	1	3.3	1	1.7
Cleft palate repair	10	33.3	7	23.3	17	28.3
Lymph Node Excision	1	3.3	0	0	1	1.7
Palatal fistula repair	0	0	1	3.3	1	1.7
Tongue tie release	0	0	1	3.3	1	1.7
Tongue Flap	1	3.3	0	0	1	1.7
Urethroplasty	0	0	1	3.3	1	1.7

Table-1: Table showing different surgical procedures in two study groups

	Emergence & Recovery Characteristics	Group I (Halothane) (n=30)		Group II (Sevoflurane) (n=30)		Statistical Significance	
		No.	%	No.	%	" χ^2 "	"p"
1.	Coughing	2	6.7	2	6.7	0	1
2.	Breath holding	2	6.7	1	3.3	0.351	0.554
3.	Laryngospasm	0	0	1	3.3	1.017	0.313
4.	Bronchospasm	0	0	1	3.3	1.017	0.313
5.	Excitement	1	3.3	11	36.7	10.417	0.001
6.	Rise in temperature	0	0	0	0	-	-
	Overall	5/180	2.78	16/180	8.89	6.119	0.013

Table 2: Complications during Emergence and Recovery in two groups

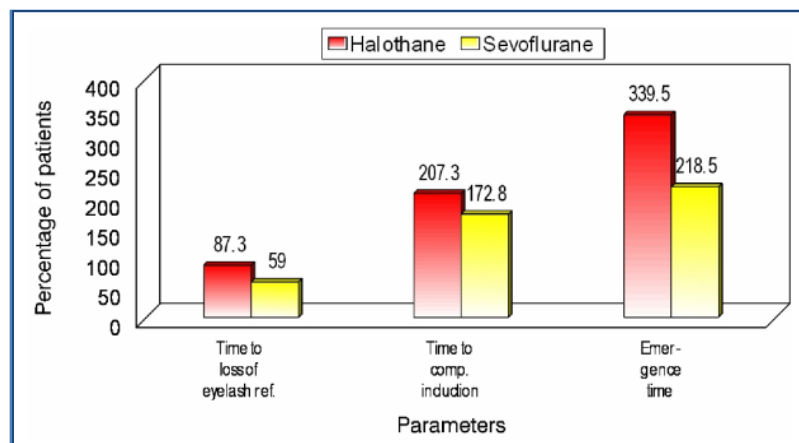
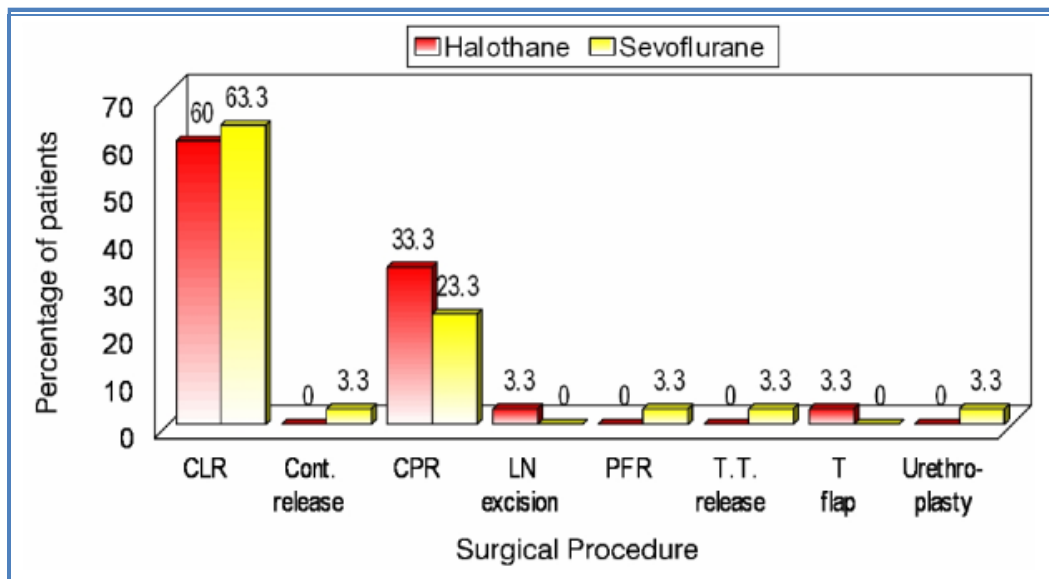
S.N.	Post-operative complications	Group I (Halothane) (n=30)		Group II (Sevoflurane) (n=30)		Statistical Significance	
		No.	%	No.	%	" χ^2 "	"p"
1.	Nausea	0	0	3	10	3.158	0.076
2.	Vomiting	2	6.7	6	20	2.308	0.129
3.	Shivering	8	26.7	0	0	9.231	0.002
4.	Hypothermia	1	3.3	0	0	1.017	0.313
5.	Dysrhythmia	1	3.3	0	0	1.017	0.313
6.	Desaturation	0	0	0	0	-	-
	Overall	12/180	6.67	9/180	5	0.455	0.500

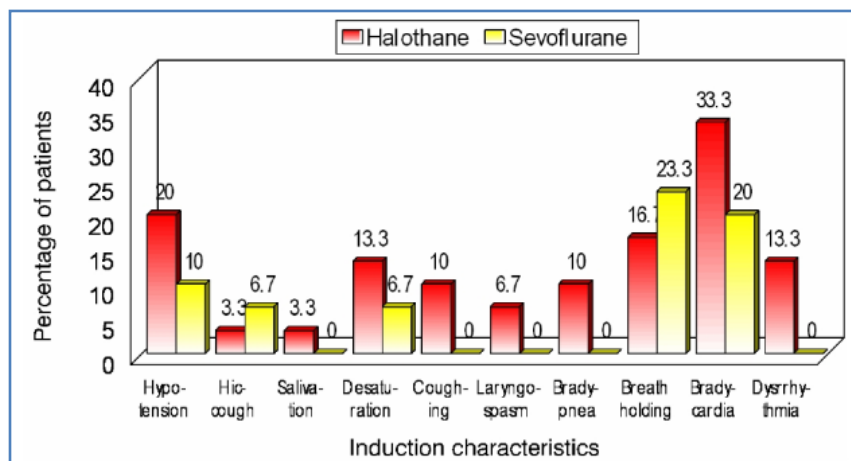
Table 3: Comparison of Post-operative complications in two groups

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S. No.	Parameter	Group I (Halothane)		Group II (Sevoflurane)		Statistical Significance	
		Mean	SD	Mean	SD	"t"	"p"
1.	Time to Loss of eyelash reflex	87.3	16.8	59.0	12.8	7.356	<0.001
2.	Time to Complete Induction	207.3	29.7	172.8	22.0	5.116	<0.001
3.	Emergence Time	339.5	95.8	218.5	45.7	6.244	<0.001

Table 4: Comparison of time of Induction and Emergence in two groups (seconds)





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