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SCIENTIFIC ARTICLE

Comparison of sevoflurane concentration for insertion of proseal laryngeal mask airway and tracheal intubation in children (correlation with BIS)☆

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KEYWORDS
Sevoflurane;
Proseal laryngeal mask airway;
Endotracheal tube;
Bispectral index monitor

Abstract
Background: Sevoflurane is an inhalational agent of choice in paediatric anaesthesia. For management of airways in children a suitable alternative to ETT is a paediatric proseal laryngeal mask airway (benchmark second generation SAD). Various studies have shown that less sevoflurane concentration is required for LMA insertion in comparison to TI. BIS is a useful monitor of depth of anaesthesia.
Aims: To compare concentration of sevoflurane (end tidal and MAC value) required for proseal laryngeal mask airway insertion and tracheal intubation in correlation with BIS index.
Method: The prospective randomised single blind study was done in children between 2 and 9 years of ASA I and II and they were randomly allocated to Group P (proseal laryngeal mask airway insertion) and Group TI (tracheal intubation). No sedative premedication was given. Induction was done with 8% sevoflurane and then predetermined concentration was maintained for 10 min. Airway was secured either by proseal laryngeal mask airway or endotracheal tube without using muscle relaxant. End tidal sevoflurane concentration, MAC, BIS, and other vital parameters were monitored every minute till insertion of an airway device. Insertion conditions were observed. Statistical analysis was done by ANOVA and Students *t* test.
Results: Difference between ET_{LMI} (2.49 ± 0.44) and ET_{TI} (2.81 ± 0.65) as well as MAC_{LMI} (1.67 ± 0.13) and MAC_{TI} (1.77 ± 0.43) was statistically very significant, while BIS_{LMI} (49.05 ± 10.76) and BIS_{TI} (41.25 ± 3.25) was significant. Insertion conditions were comparable in both the groups.

☆ Study done at Department of Anaesthesiology, Medical College and SSG Hospital, Vadodara, India.

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Conclusion: We can conclude that in children airway can be secured safely with proseal laryngeal mask airway using less sevoflurane concentration in comparison to tracheal intubation and this was supported by BIS index.

PALAVRAS-CHAVE
Sevoflurano;
Máscara laríngea proseal;
Tubo endotraqueal;
Monitor do índice bispectral

Comparação da concentração de sevoflurano para a inserção de ML proseal e intubação traqueal em crianças (correlação com BIS)

Resumo
Justificativa: Sevoflurano é um agente inalatório de escolha em anestesia pediátrica. Para o manejo de vias aéreas em crianças, uma alternativa adequada para o TET é uma MLP pediátrica (referência de segunda geração SAD). Vários estudos mostraram que uma menor concentração do sevoflurano é necessária para a inserção da ML em comparação com a IT. O BIS é um monitor útil da profundidade da anestesia.
Objetivos: Comparar a concentração de sevoflurano (valores ao final da expiração e da CAM) necessária para a inserção de MLP e intubação traqueal em correlação com o BIS.
Método: Estudo prospectivo, randômico e cego conduzido com crianças entre 2-9 anos de idade, estado físico ASA I-II, randomicamente alocados nos grupos P (inserção de MLP) e IT (intubação traqueal). Pré-medicação sedativa não foi administrada. A indução foi realizada com sevoflurano a 8% e, em seguida, a concentração predeterminada foi mantida durante 10 min. A via aérea foi garantida por MLP ou tubo endotraqueal, sem o uso de relaxante muscular. A concentração de sevoflurano ao final da expiração, CAM, BIS e outros parâmetros vitais foram monitorados a cada minuto até a inserção do dispositivo respiratório. As condições de inserção foram observadas. A análise estatística foi realizada com o teste-*t* de Student e ANOVA.
Resultados: As diferenças entre TE_{IML} ($2,49 \pm 0,44$) e TE_{IT} ($2,81 \pm 0,65$), bem como CAM_{IML} ($1,67 \pm 0,13$) e CAM_{IT} ($1,77 \pm 0,43$) foram estatisticamente muito significativas; enquanto BIS_{IML} ($49,05 \pm 10,76$) e BIS_{IT} ($41,25 \pm 3,25$) foram significativos. As condições de inserção foram comparáveis em ambos os grupos.
Conclusão: Podermos concluir que a MLP em comparação com a intubação traqueal pode ser segura para a via aérea de crianças, usando menos concentração de sevoflurano, o que foi confirmado pelo BIS.

Introduction

Sevoflurane inhalation anaesthesia is considered gold standard in children as it provides fast, safe and accurate control of anaesthesia depth combined with security of quality recovery. LMA is widely used for anaesthesia in children with advantages over tracheal tube in terms of stress response to insertion and removal of device and fewer post operative complications like coughing and sore throat.[1] Second generation supraglottic airway (SAD), viz. proseal LMA with higher seal pressure, has become the benchmark device.[2] Previous studies have shown that less sevoflurane is required for LMA insertion than laryngoscopy and tracheal intubation.[1,3,4] More recently BIS monitor is used as clinical marker of hypnosis and various workers have used BIS index to study the sevoflurane concentration.[5,6] The literatures of Medline did not show any study which has correlated the sevoflurane concentration required for LMA insertion and laryngoscopy and tracheal intubation using BIS monitor. So we designed a study to determine and compare the minimum sevoflurane concentration for insertion of PLMA and tracheal intubation in paediatric patients in correlation with BIS.

Methods

This was a randomised, prospective, comparative study and was approved by the institutional ethical committee and a written informed consent was obtained from the children's parents.

The study population consisted of sixty patients aged between 2 and 9 years, weighing 9–25 kg of ASA I/II posted for lower abdominal surgeries of short duration. Children with recent upper respiratory tract infection anticipated difficult airway, full stomach and any systemic or psychological disorders were excluded from the study. Using an envelope method, children were randomly allocated into two groups (30 each).

Group P ($n_p = 30$): Proseal Laryngeal Mask Airway (PLMA) insertion group
Group TI ($n_{ti} = 30$): Tracheal intubation group

After thorough preanaesthetic checkup, written and informed consent was obtained from parents and NBM status of child was confirmed. Intravenous glycopyrrolate 20 μg/kg was given 20 min before induction. No sedative premedication was given.

Compact airway module of anaesthesia machine was used to measure sevoflurane concentration (end tidal and MAC) and other vital parameters. For measurement of BIS index, adult disposable biosensor strips were attached. It consists of 4 gel electrodes, the proximal lead was placed above the nasion and the distal lead was placed midway between tragus of the ear and outer canthus of the eye.

Baseline parameters like pulse rate, blood pressure, oxygen saturation, respiratory rate, Et CO_2 and BIS were noted.

Anaesthesia was conducted in conventional manner by an anaesthesiologist who was blinded for BIS value as well as end tidal sevoflurane concentration. General anaesthesia was induced with inhalation of sevoflurane 8% with (50:50) $O_2 + N_2O$ using Jackson Rees circuit for children below 20 kg and Bain's circuit for children above 20 kg. Various studies have shown that PLMA insertion requires less concentration of sevoflurane in comparison to tracheal intubation and hence we started with predetermined concentration of 2% in group P while 2.5% in group TI. After the loss of eye lash reflex, anaesthesia was maintained with the predetermined end tidal sevoflurane concentration for 10 min[1,3,5] (Table 1) to allow adequate time for sevoflurane partial pressure to achieve equilibrium in alveoli and brain. IPPV was given if depths of respiration decrease and end tidal CO_2 more than 45 mm Hg. At the end of 10 min the attempt was made either to insert PLMA or tracheal tube without using muscle relaxant. According to the weight of the child, size of airway device was selected. PLMA was inserted using index finger technique. Proper placement of the PLMA and tracheal tube was confirmed with bilateral equal air entry and square wave capnography.

If the attempt failed to secure airway the end tidal sevoflurane was increased by 0.5% and another 10 min was allowed to elapse before the next attempt. If this second attempt also failed, it was decided for no further attempts to be made but procedure to be completed by using conventional method of intubation using muscle relaxant and this child was excluded from the study.

The conditions during insertion and intubation were evaluated and graded as excellent, satisfactory and poor. Number of attempts in each patient was also noted down along with insertion conditions.

The sevoflurane concentration and BIS values were recorded by an observer from induction at an interval of 1 min till the airway is secured either by PLMA or tracheal tube.

Vital parameters (heart rate, blood pressure, SPO_2) and any complications like laryngospasm, bronchospasm during insertion of airway gadget were recorded by the observer.

The study ended once airway gadget was secured.

Anaesthesia was maintained with $O_2 + N_2O$ (50:50) with sevoflurane in conventional manner without using muscle relaxant by the same clinician who inserted PLMA or intubated. Patients were monitored throughout the perioperative period till their stay in the post anaesthesia care unit (PACU).

Table 1 Predetermined concentration of sevoflurane in relation with age.

Wt in kg	Predetermined end tidal sevoflurane concentration	
	Group P	Group TI
9–10	2%	2.5%
10–15	2.5%	3%
>20	3%	3.5%

Statistical analysis

As our pilot study was with no previous information being available regarding expected means or standard deviations, a pre-study power calculation was not possible. The number of participants was based on a feasible convenience sample and was therefore arbitrarily decided. The primary outcome was to compare sevoflurane concentration for insertion of proseal LMA and tracheal intubation in children. Secondary outcomes were to compare haemodynamic changes and complications during insertion of airway gadgets. Statistical testing of ordinal data (ratio of male and female, age of the patient, weight of the patients, and type of surgery) was done using Fisher's exact test. The remaining variables were analysed for statistical significance using two tailed unpaired *t* test. The results are presented as mean ± standard deviation (SD), number (%) of cases. A *p*-value of <0.05 was considered significant.

Results

Demographic data like age, weight, ASA were comparable in both the groups as shown in Table 2. Male preponderance was seen in both the groups because of selection of surgery. Duration of surgery was short and comparable in both the groups.

Induction time (time to loss of eye lash reflex) was comparable in both the groups. PLMA was inserted in single attempt in all the cases. In group TI tracheal intubation was

Table 2 Demographic data.

	Group P	Group TI	*p*-Value
Age (yrs)	5.65 ± 3.10	4.6 ± 1.46	>0.05
Weight (kg)	14.40 ± 4.96	11.65 ± 1.76	>0.05
Gender			
Male	19	18	>0.05
Female	1	2	>0.05
ASA grade			
I	18 (90%)	17 (85%)	>0.05
II	2 (10%)	3 (15%)	>0.05

Table 3 End tidal sevoflurane concentration at various phases of induction and insertion.

Stages	Group P	Group TI	*p*-Value
Induction	6.35 ± 1.06	5 ± 1.45	>0.05
After predetermined concentration			
0 min	3.82 ± 1.41	3.97 ± 1.31	>0.05
1 min	2.71 ± 0.47	2.87 ± 0.67	>0.05
2 min	2.53 ± 0.43	2.81 ± 0.65	<0.01
3 min	2.47 ± 0.45	2.83 ± 0.65	<0.01
4 min	2.46 ± 0.46	2.81 ± 0.65	<0.01
5 min	2.43 ± 0.45	2.82 ± 0.64	<0.01
6 min	2.47 ± 0.44	2.82 ± 0.64	<0.01
7 min	2.47 ± 0.45	2.82 ± 0.4	<0.01
8 min	2.46 ± 0.47	2.81 ± 0.64	<0.01
9 min	2.47 ± 0.44	2.81 ± 0.64	<0.01
10 min (insertion)	2.49 ± 0.44	2.81 ± 0.65	<0.01

Table 4 MAC of sevoflurane at various phases of induction and insertion.

Stages	Group P	Group TI	*p*-Value
Induction	3.19 ± 0.66	2.77 ± 0.74	>0.05
After predetermined concentration			
0 min	2.31 ± 0.61	2.47 ± 0.65	>0.05
1 min	1.79 ± 0.22	1.88 ± 0.46	<0.01
2 min	1.65 ± 0.15	1.78 ± 0.42	<0.01
3 min	1.64 ± 0.12	1.79 ± 0.42	<0.01
4 min	1.65 ± 15	1.78 ± 0.42	<0.01
5 min	1.63 ± 0.15	1.80 ± 0.42	<0.01
6 min	1.68 ± 0.16	1.78 ± 0.42	<0.01
7 min	1.65 ± 0.15	1.78 ± 0.42	<0.01
8 min	1.65 ± 0.14	1.76 ± 0.42	<0.01
9 min	1.67 ± 0.12	1.77 ± 0.42	<0.01
10 min (insertion)	1.67 ± 0.13	1.77 ± 0.43	<0.01

done at first attempt in 85% of the cases and in remaining 15% second attempt was required. However, the difference was statistically insignificant ($p > 0.05$).

End tidal sevoflurane concentration was comparable in both the groups at the time of induction (Table 3). The difference in two groups was not significant for first two minutes but it started becoming significant from end of two minutes onwards till the insertion of airway device. At the time of insertion/intubation ET_{LMI} was 2.49 ± 0.44 and ET_{TI} was 2.81 ± 0.65 and thus the difference was statistically very significant. Similarly MAC_{LMI} was 1.67 ± 0.13 and MAC_{TI} was 1.77 ± 0.43 and thus the difference was statistically very significant (Table 4). BIS was comparable in both the groups up to 8 min after induction but there was statistically significant difference between two groups at the time of insertion of airway device, viz. in group P it was 49.05 ± 10.76 and in group TI it was 41.25 ± 3.25 ($p < 0.05$) (Table 5).

Insertion conditions were comparable in both the groups and grading. Vital parameters like pulse, mean BP, respiratory rate, SpO_2, EtN_2O and $EtCO_2$ were comparable in both the groups throughout the observation period.

Discussion

Two inventions in 1981, viz. sevoflurane (inhalational agent) and laryngeal mask airway (LMA), have brought radical change in management of paediatric anaesthesia. Advantages of LMA over TI in paediatric patients have been studied previously.[1,2,7] Proseal LMA is superior to classic LMA in terms of higher seal pressure with safety of controlled ventilation in children. Paediatric PLMA with revised cuff profile and two tube results into more secure anchoring of the device in place. These features make the PLMA ideal for use in children.[2] Thus safety and efficacy in paediatric patients have been increased. The PLMA has yet to be outperformed by any other SAD, making it premier SAD in children. Thus, we designed our study in children to compare sevoflurane concentration in terms of end tidal sevoflurane and MAC of sevoflurane for insertion of PLMA and TI. Uniqueness of our

Table 5 BIS value at various phases of induction and insertion.

Stages	Group P	Group TI	*p*-Value
Pre induction	94.35 ± 2.50	93.60 ± 2.80	>0.05
Induction	81.05 ± 10.69	81.75 ± 7.95	>0.05
After predetermined concentration			
0 min	38.80 ± 17.53	35.50 ± 12.71	>0.05
1 min	40.11 ± 16.25	35.40 ± 11.62	>0.05
2 min	43 ± 14.61	40.75 ± 7.59	>0.05
3 min	41.75 ± 14.06	45.30 ± 8.63	>0.05
4 min	40.45 ± 14.75	44.40 ± 6.41	>0.05
5 min	45.21 ± 14.14	43.85 ± 6.49	>0.05
6 min	46.47 ± 13.53	43.10 ± 6.79	>0.05
7 min	47.89 ± 12.6	43.15 ± 5.03	>0.05
8 min	47.37 ± 12.02	42.75 ± 5.64	>0.05
9 min	48.63 ± 11.07	41.95 ± 5.93	<0.05
10 min (insertion)	49.05 ± 10.76	41.25 ± 3.25	<0.05

study is that we included BIS index as clinical marker of hypnosis for the comparison.[5,8]

Comparing sevoflurane concentration at the time of insertion of airway device significant difference was observed in end tidal sevoflurane concentration as well as MAC value. End tidal sevoflurane concentration at insertion of PLMA, i.e. ET_{LMI} 2.49 ± 0.44 was lower in comparison to ET_{TI} 2.81 ± 0.65. MAC_{LMI} 1.67 ± 0.13 was also lower in comparison to MAC_{TI} 1.77 ± 0.43. Our findings are similar to other studies.[1,3,4]

BIS value in group P during insertion was 49 ± 10.76 whereas in TI group it was 41.25 ± 3.25 and the difference was statistically significant. Our findings are in consonance with other studies.[6]

Thus less sevoflurane is required for PLMA insertion in comparison to TI. This was supported by BIS value, which was higher indicating lesser depth of anaesthesia for PLMA insertion.

In our study insertion conditions for PLMA and TI were comparable. Our findings are same as those of Aantaa et al.[1] and Patel et al.[9]

Thus we concluded that in children, airway can be secured safely and effectively with PLMA using less sevoflurane concentration in comparison to tracheal intubation which was supported by BIS index. Thus, PLMA can be the airway of choice for procedures where there is no need of deep level of anaesthesia.

Conflicts of interest

The authors declare no conflicts of interest.

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