

Effect of airway device and depth of anesthesia on intra-ocular pressure measurement during general anesthesia in children: A randomized controlled trial

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Abstract

Background and Aims: Accurate measurement of intraocular pressure (IOP) under anaesthesia is essential for diagnosis and further management of pediatric glaucoma patients. However, depth of anaesthesia and use of airway device like laryngeal mask airway (LMA) or endotracheal tube can influence IOP values measured. We planned this study to compare change of IOP with facemask or LMA. Change of IOP at varying depth of anaesthesia was also assessed.

Material and Methods: After Institutional ethical clearance and informed parental consent, 89 children of glaucoma aged 0-12 years were included in this prospective randomized controlled trial. The children were randomized to facemask (Group M) and LMA (Group L). Sevoflurane was the sole general anaesthetic used in both the groups and IOP were recorded after induction, at BIS 40-60, after LMA insertion (Group L), at BIS 60-80 and BIS more than 80.

Results: The IOP values did not differ significantly between the groups at BIS 40-60 and at BIS 60-80. Moreover, pre and post LMA insertion IOP values were also comparable in Gr L ($p = 0.11$). However, significant increase in IOP values were observed with increasing BIS values within each group. The mean IOP in Group M at BIS 40-60 was 13.41 ± 4.04 as compared to 14.18 ± 3.64 at BIS 60-80 ($p = 0.003$). There was a similar pattern observed in Group L, where mean IOP at BIS 40-60 & BIS 60-80 was 14.13 ± 4.90 and 15.52 ± 4.57 respectively ($p < 0.001$).

Conclusion: Either facemask or classic LMA can be safely used as per anaesthesiologist's preference without any significant effect on IOP. BIS monitoring may be used during IOP measurement in paediatric glaucoma suspects for accurate assessment of IOP.

Keywords: Depth of anaesthesia, intraocular pressure, laryngeal mask airway

Introduction

Management of pediatric glaucoma requires accurate estimation of intraocular pressure (IOP) as the subsequent management decisions depend on the measured IOP. Limited data is available on normal pediatric IOP^[1] and

general anaesthesia is required to measure IOP in infants and small children. In our institute, examination under anaesthesia (EUA) is performed to determine the IOP at 1 week, 4 weeks, 3 months, 6 months and then repeated at 6-12 month intervals, and the target IOP is usually kept less than 15 mmHg for advanced cases and less than 18 mmHg for early-moderate glaucoma.

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How to cite this article: Darlong V, Kalaiyaran R, Baidya DK, Pandey R, Sinha R, Punj J, *et al.* Effect of airway device and depth of anesthesia on intra-ocular pressure measurement during general anesthesia in children: A randomized controlled trial. *J Anaesthesiol Clin Pharmacol* 2021;37:226-30.

Submitted: 25-Feb-2019 **Revised:** 29-Oct-2019
Accepted: 31-Dec-2019 **Published:** 15-Jul-2021

Access this article online	
Quick Response Code:	Website: www.joacp.org
	DOI: 10.4103/joacp.JOACP_55_19

Administration of general anaesthesia (GA), tracheal intubation or laryngeal mask airway (LMA) insertion and the variation in the depth of anaesthesia may influence IOP value.^[2-4] Few studies have compared the rise in IOP with the insertion of LMA to that of endotracheal tube (ETT) and found less rise in IOP following the insertion of LMA.^[3,5,6] However, even with the use of LMA the amount of rise in IOP is significant.^[3,5] Facemask should not cause significant rise in IOP as it involves further less manipulation of upper airway.

Moreover, various anaesthetic agents and change in the depth of anaesthesia can influence the measured IOP value.^[7] Dominguez *et al.* suggested that the best time may be just before arousal, when the child is still quiet and the BIS is reading light anaesthesia.^[4] However, timing of IOP measurement just before arousal may be difficult and can potentially increase airway complications from noxious stimuli in an inadequately anesthetized child.

Therefore we planned to investigate the effect on IOP with the use of classic LMA vs. facemask as the airway device and to identify the effect of varying depth of anaesthesia on IOP values.

Our hypothesis is that facemask technique will cause less rise in IOP compared to LMA and reduce false positive cases and depth of anaesthesia monitoring will identify appropriate depth required for measuring IOP and reduce falsely low IOP values at deeper plane of anaesthesia.

The primary objective was to measure IOP with the use of facemask and LMA. The secondary objective was to measure IOP at different depth of anaesthesia as measured by BIS value.

Material and Methods

The study was approved by the Institutional Ethics Committee (IEC/NP-125/11.04.2014, RP-52/2014) and the trial was registered in clinical trial registry of India (CTRI/2017/11/010580). After informed parental consent, American Society of Anesthesiology (ASA) physical status I and II children aged between 0 and 12 years, coming for IOP measurement for suspected or known glaucoma, were enrolled in our study. The period of recruitment was from 31st December 2014 till 21st December, 2016. A computer generated randomization sequence was used for randomization into two groups: Group M – Receiving GA with facemask and Group L – Receiving GA with classic LMA. Allocation concealment was done by sequentially numbered opaque envelope technique and allocation ratio was 1:1. Exclusion criteria were: ASA physical status III and more, emergency

ophthalmic procedure, active respiratory tract infection, anticipated difficult airway, other airway abnormalities (e.g., laryngomalacia, subglottic stenosis), active gastrointestinal reflux, lung disease requiring high airway pressure to achieve minute ventilation. Patients were excluded after induction of anaesthesia if there was difficulty in maintaining airway patency with face-mask and LMA was required to be inserted in the Group M and if there were more than one attempt for LMA insertion in Group L. Moreover, patients requiring insertion of oropharyngeal airway in any of the groups were also excluded.

All the children were shifted to operating room accompanied by either of the parent. No premedication was given. Standard monitoring including electrocardiogram (ECG), non-invasive blood pressure (NIBP) and pulse oximetry (SpO₂) were attached. Anaesthesia was induced with inhalation of sevoflurane increasing gradually from 2 to 8%, in oxygen at a fresh gas flow of 6 L/min. At the loss of eyelash reflex, intravenous (IV) cannula was inserted and a sensor strip for measuring Bispectral Index (BIS value; Covidien, USA) was attached to the forehead of the child after cleaning the area with antiseptic solution. Proparacaine local anaesthetic eye drop was instilled to provide intraoperative analgesia. IOP was measured with the use of applanation tonometry (Perkins) by a senior ophthalmologist regularly performing this procedure. The ophthalmologist was blinded to the anaesthetic depth but could not be blinded to airway device used.

In Group M, anaesthesia was maintained with O₂/N₂O (50:50) at a flow rate of 6 L/min and sevoflurane with facemask. Sevoflurane was initially titrated to achieve and maintain BIS value between 40 and 60 with spontaneous ventilation. IOP was measured when the BIS value was between 40 and 60, and then sevoflurane and N₂O were switched off. IOP were measured again during recovery at BIS ranging between 60 and 80 and at more than 80.

In Group L, after IV cannulation classic LMA of appropriate size was inserted and proper position of LMA was confirmed by end tidal CO₂ monitoring. IOP was measured just before and after the LMA insertion. If two or more attempts were required for correct placement of LMA, the child was excluded from the study. Anaesthesia was maintained with O₂/N₂O mixture 50:50 and sevoflurane was titrated to achieve and maintain a BIS value 40-60 with spontaneous ventilation similar to the technique as described above. IOP was measured at BIS value 40 and 60 and then similarly during recovery at BIS 60 to 80, and more than 80. At the end of the procedure oropharyngeal suctioning was done and LMA was removed when the child was awake.

Hemodynamic parameters such as heart rate (HR), blood pressure (BP) and end tidal CO₂ (EtCO₂) were also recorded simultaneously after induction of anaesthesia, after LMA insertion and thereafter every two minutes. Intraoperative hypotension or hypertension or tachycardia was defined as more than 20% change from the baseline values recorded.

Since there is no previous study available in the literature, comparing these two techniques for measuring IOP, we did a pilot study of 10 cases to calculate the sample size. The average IOP found in the pilot survey was 8.4 ± 3.9 mmHg in the facemask group and 11.3 ± 4.2 in the classic LMA group. The rise in IOP was 2.9 mmHg (35%) in the classic LMA group. To detect a minimum of 25% rise (absolute 2.1 mmHg) with a population SD of 4 mm Hg, 40 patients were needed in each group in a two sided t test with a power of 90% and 5% type I error in paired t test. Considering a drop out of 10%, n = 89 patients were recruited.

Data were analysed using SPSS version 23.0 (IBM Corporation, Chicago, USA). Continuous variables following normal distribution were analysed by paired t-test and categorical variables were compared by Chi-Square test and Fisher's exact test. Data were presented in Mean ± SD, mean difference and 95% confidence interval. *P* < 0.05 was considered statistically significant.

Results

A total of 89 patients were included in the study, 43 in Group M and 46 in Group L as depicted in the CONSORT diagram [Figure 1]. Both the groups had comparable demographic parameters [Table 1]. The IOP values did not differ significantly between the groups when measured at BIS 40-60 and at BIS 60-80 [Table 2]. Moreover, pre- and post-LMA insertion IOP values were also comparable in Gr L (*p* = 0.11). However, significant increase in IOP values were observed with increasing BIS values within each group [Table 3].

IOP recording at BIS >80 could be performed only in 5 patients in Group M and 4 patients in Group L as children started moving at BIS >80 and the data were considered insufficient. There was no episode of hypotension following induction of anaesthesia in any group. There was no episode of any tachycardia or hypertension following LMA insertion in Group L and in any other time point intra-operatively in any group. There was no airway related complications and post-operative nausea vomiting in any of the groups.

Table 1: Demographic parameters

Parameter	Group M (n=43)	Group L (n=46)	P
Age (years)	3.74 (1.2-11)	2.77 (0.5-9)	0.45
Sex (male/female)	27/16	25/21	0.41

Age in mean (SD)

Table 2: IOP measurement (mmHg) between the two groups

IOP	FM Mean±SD (95% CI)	LMA Mean±SD (95% CI)	Mean difference (95% CI)	P
BIS 40-60	13.41±4.04 (12.17-14.66)	14.13±4.90 (12.67-15.58)	0.71 (2.61-1.18)	0.45
BIS 60-80	14.18±3.64 (13.06-15.30)	15.52±4.57 (14.16-16.88)	1.33 (3.08-0.41)	0.13

Student's t test

Table 3: IOP measurement (mmHg) at different BIS values within the group

Parameter	IOP (BIS40-60) Mean±SD	IOP (BIS60-80) Mean±SD	Mean Difference (95% CI)	P
Group M (n=43)	13.41±4.04	14.18±3.64	0.77 (0.26-1.26)	0.003
Group L (n=46)	14.13±4.90	15.52±4.57	1.39 (0.90-1.87)	<0.001

Paired t test

Discussion

In this prospective randomized controlled study, we demonstrated a significant fall in IOP with increasing depth of anaesthesia regardless of the airway device used, where sevoflurane was used as a sole anaesthetic agent. However, use of LMA over facemask did not increase IOP significantly. Factors known to influence IOP measurement under general anaesthesia are head and neck position, anaesthetic agent used, airway device used and hemodynamic condition post induction.^[8] In the present study, head and neck positions were kept neutral and sevoflurane was the sole anaesthetic agent used in all the cases. Moreover, there was no episode of intraoperative hypotension or hypertension in any case, and no difference in hemodynamic parameters in pre and post LMA insertion.

Although BIS monitoring has clear advantages like early recovery, less postoperative nausea and vomiting, less consumption of anaesthetic agents, increased cost precludes its use in routine practice.^[9,10] However, targeted BIS therapy to achieve desired effect has been found to be beneficial in specific clinical context. Use of BIS monitoring to decrease incidence of oculo-cardiac reflex in squint surgery in children^[11] and delivery of electrical current at a targeted BIS range to optimize seizure quality during modified electro-convulsive therapy are such examples.^[12] Similarly, identifying optimum BIS value at which IOP is least affected

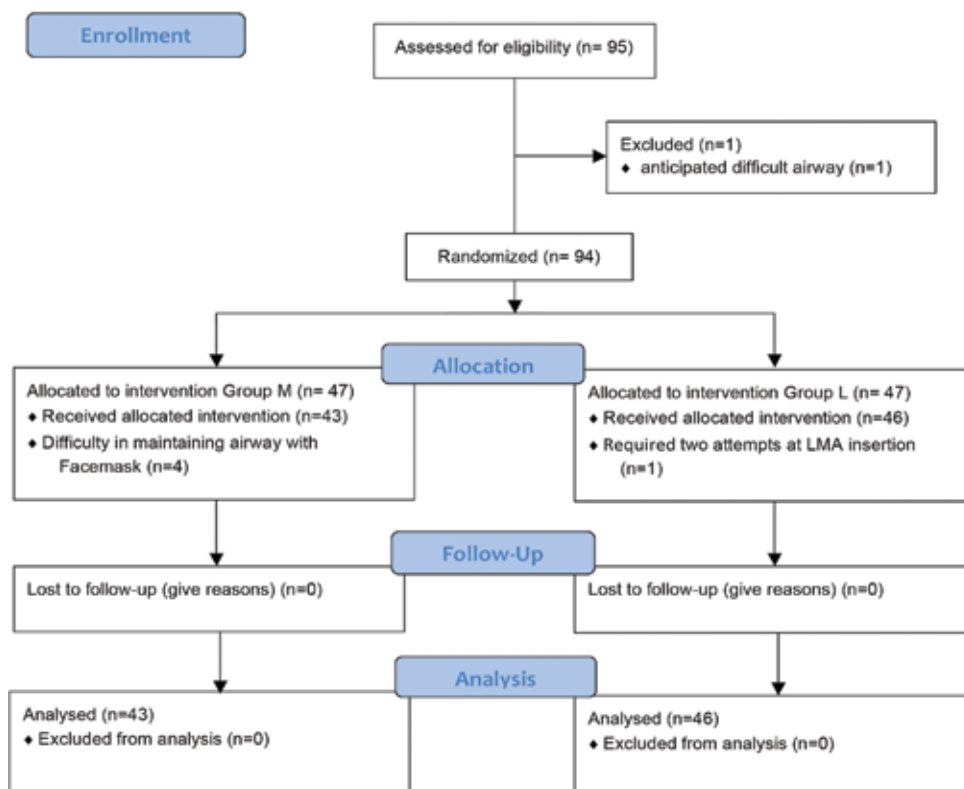


Figure 1: CONSORT Flow Diagram

by anesthesia may provide more accurate management options and prognosis in children with congenital glaucoma. In this study, we found significant decrease in IOP values at BIS 40-60 as compared to BIS 60-80 irrespective of airway device used. Therefore, BIS monitoring should be considered whenever available and BIS 60-80 may be targeted for accurate IOP measurement. Although BIS monitoring have demonstrated a good correlation with level of sedation and anesthesia in paediatric patients, there is controversy with interpretation of BIS value in infants less than 6 months of age.^[13] In the current study only one patient was less than 6 months old infant.

Incidence of congenital glaucoma is 1 in 10000 live births.^[14] Regular accurate assessment and long term follow up is very much essential in patients with high risk factors like suspicious optic discs, cup-to disc (C/D) ratio of ≥ 0.6 , asymmetry more than 0.2 between the two eyes, narrow neuroretinal rim, persistently elevated IOP of ≥ 21 mmHg, family history of glaucoma in the parents or sibling, diagnosis of congenital glaucoma in the other eye, history of blunt trauma to either eye and conditions associated with glaucoma such as Sturge-Weber syndrome or Axenfeld-Rieger syndrome.^[15] In the current study, measured IOP value is found to vary with the depth of anesthesia. Therefore, accurate IOP assessment under targeted optimum depth of anesthesia with BIS monitoring can be justified in certain selected high-risk

population, where management depends on the accuracy of measured IOP.

Choice of airway device can influence the measured IOP independent of depth of anesthesia. Agrawal and colleagues^[3] compared the effects of ProSeal LMA versus ETT on IOP and hemodynamic response in paediatric patients. They found a significant rise in IOP in both the groups. However quantum of rise was less in Proseal LMA group. However, other studies using classic LMA did not find a significant increase in IOP following LMA insertion^[5,6,16,17] similar to our study. Proseal LMA being a second generation LMA with a larger cuff may presumably produce increased hemodynamic and IOP response.

On the contrary, Watts *et al.*^[18] found a small but significant increase in IOP after LMA insertion in children. They recommended that the ideal time to measure IOP in children would be just after induction with facemask *in situ* and before the insertion of LMA. This could be the best possible time since we avoid eliciting the minimal sympathetic stimulation caused due to airway manipulation by LMA. However, we apprehend increased depth of anesthesia just after induction can produce false low values of IOP, and therefore gives rise to false negative cases. Besides, increased IOP values following LMA insertion documented in this study were also within the normal limits exhibiting minimal clinical significance.

Sevoflurane in O₂/N₂O mixture via facemask was used for IOP measurement in children by Dominguez *et al.*,^[4] and they noticed a fall in IOP after sevoflurane induction. They concluded that the best time to measure IOP in children receiving sevoflurane is just before arousal, when the child is still quiet, sevoflurane is almost fully eliminated and the BIS is reading light plane of anesthesia. However, in our clinical experience, ocular manipulation at light plane of anesthesia (BIS >80) is difficult as we could not measure IOP in most of the patients at BIS >80. Moreover, this can potentially lead to adverse complications including laryngospasm, bronchospasm and sympathetic stimulation leading to fallacious high values of IOP, particularly at the hands of trainee ophthalmologists requiring more time to measure IOP.

Any attempt at measuring IOP only under facemask may have other adverse consequences like inadequate access to eye, chances of direct compression of eye and corneal abrasion, operation theatre pollution, cost effectiveness with regards to usage of inhalational agent at higher flows, difficulty in maintaining proper depth of anesthesia and early fatigue of anesthesia provider. Since the rise in IOP with classic LMA is minimal and not clinically significant, classic LMA may be considered a better device than facemask for anesthesia administration for IOP measurement. Moreover, it may be easier to maintain a target BIS of 60-80 with the use of a classic LMA as compared to facemask. However, classic LMA also has problems like increased anesthesia time, increased anesthetic requirement to insert LMA etc.

The study had several limitations. Firstly, BIS is not a very reliable depth of anesthesia monitor in children and this is the major limitation. Secondly, correct recording of MAC value was not possible in facemask group and therefore MAC could not be correlated with BIS.

To conclude, either facemask or classic LMA can be safely used as per anesthesiologist's preference without any significant effect on IOP. BIS target of 60-80 may be followed during IOP measurement in paediatric glaucoma suspects for accurate assessment of IOP.

Financial support and sponsorship

This study was funded by All India Institute of Medical Sciences, New Delhi.

Conflicts of interest

There are no conflicts of interest.

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