

## RANDOMIZED CONTROLLED TRIAL TO COMPARE THE CHANGES IN HEMODYNAMICS AND INTRAOCULAR PRESSURE USING ENDOTRACHEAL INTUBATION AND I-GEL FOLLOWING INDUCTION OF ANAESTHESIA IN CHILDREN UNDERGOING OPHTHALMIC SURGERY

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### Abstract

**Background:** Intraocular pressure (IOP) and hemodynamic parameters may rise due to unfavourable sympathetic stimulation brought on by the insertion of the advanced airway during the induction of general anaesthesia. This study aimed to compare the effects on IOP and cardiovascular response to endotracheal intubation and I-gel following induction of anaesthesia in children undergoing ophthalmic surgery. **Materials and Methods:** This prospective, randomized, controlled trial was conducted at the Regional Institute of Ophthalmology and Government Ophthalmic Hospital, Egmore, Chennai, for one year (Jan 2022-Dec 2022) on 50 children undergoing ophthalmic surgery. Patients were divided into Group E (Endotracheal intubation) and Group I (I-gel insertion). At the preoperative stage, following the initial injection of the anaesthetic drug, immediately after the insertion of the airway device—endotracheal tube and I-Gel, 2 minutes after the insertion of the airway device, and 5 minutes after the insertion of the airway device—the hemodynamic parameters of blood pressure, heart rate, and oxygen saturation were measured and compared. **Results:** Although there was no statistically significant difference in the preoperative IOP between the two groups, the post-operative IOP was 11.32 mmHg in Group E and 9.72 mmHg in Group I. After the advanced airway was inserted, Group E's mean heart rates, systolic, diastolic, and mean blood pressure, and the incidence of post-operative nausea and vomiting were considerably greater than in Group I. **Conclusion:** Compared to inserting an endotracheal tube, the insertion of the i-gel device improves IOP and the haemodynamic system stability in children undergoing ophthalmic surgery.

## INTRODUCTION

Vision is one of the most essential special senses in humans. Visual impairment affects quality-adjusted life years, socioeconomic status, daily activities and mental health.<sup>[1]</sup> Early diagnosis and treatment help reverse vision impairment, as in congenital cataracts, glaucoma, squint, ptosis, dacryocystitis, ocular injuries and corneal repair.<sup>[2]</sup> Anaesthesia helps patients undergo surgery comfortably, safely and with better pain relief. Most commonly, ophthalmic surgeries in the paediatric population are performed under general anaesthesia.<sup>[3]</sup> The main

factors to take into account while managing anaesthesia for ophthalmic procedures is a fixed eye with akinesia of the extraocular muscles, airway control with sufficient breathing, stable hemodynamics, controlled intraocular pressure by preventing an increase in central and venous pressure before, and during, and after the procedure.<sup>[4]</sup> There is no effect on how the operation will go in a treatment requiring only extraocular surgery. The ophthalmic surgeon manometrically manages the intraocular pressure (IOP) during a closed intraocular surgery. It is vital to maintain control of IOP during open ophthalmic operations.

When the sclera is surgically cut, the IOP is roughly comparable to the ambient pressure, and before a surgical incision, a low-normal IOP is preferred.<sup>[5]</sup>

A hypertensive eye's sudden decompression might result in catastrophic complications such as iris or lens prolapse, vitreous loss, or expulsive choroidal haemorrhage. The anesthesiologist has unique problems during these operations, and while treating penetrating eye injuries, effective anaesthesia administration is crucial to a good surgical outcome.<sup>[6]</sup> Generally, general anaesthesia is used for most paediatric ophthalmic procedures. Endotracheal intubation during general anaesthesia is a tried-and-true technique widely used worldwide. Throughout the years, the process has changed. Pressor reaction and increased intraocular pressure are related to laryngoscopy and endotracheal intubation. Its defining characteristics are its increased heart rate, a brief rise in blood pressure, and an elevation in IOP.<sup>[7]</sup> Although this phenomenon is transient and returns to normal, healthy patients do not notice it. Both pharmacological and non-pharmacological approaches have been tried to obtund such a reaction. Normally, a closed eye can sustain a brief rise in IOP. If glaucoma is already present, a rise in IOP may exacerbate the condition of the blood supply and lead to additional loss of visual acuity and field. If the IOP is higher, the iris may prolapse through the incision.<sup>[8]</sup>

A relatively new supraglottic device, the i-gel has an anatomically tailored mask constructed of a transparent, soft thermoplastic elastomer that resembles gel. It is a cutting-edge thermoplastic elastomer second-generation airway device. It doesn't cause the cuff to swell up because it is a soft and loose style.<sup>[9]</sup> Due to its anatomical design, I gel functions correctly on the peri laryngeal and hypopharyngeal structures. I-gel has become a popular airway device due to its simplicity, ease of insertion, lack of movement, reduced risk of soft tissue injury, and lower price. The patient experiences less stress since I-gel is inserted into the hypopharynx rather than the trachea. Since there is no inflated cuff, it is simple to use, stable after insertion, and less likely to have stimulatory effects from tissue compression. Studies on how its insertion affects IOP and the cardiovascular system are still scarce, despite its rising use.<sup>[10]</sup> The study aimed to compare the changes in hemodynamics and intraocular pressure using Endotracheal intubation and I gel following induction of anaesthesia in children undergoing ophthalmic surgery.

## MATERIALS AND METHODS

This prospective, randomized, controlled trial was conducted at the Regional Institute of Ophthalmology and Government Ophthalmic Hospital, Egmore, Chennai, for one year (Jan 2022-Dec 2022) on 50 children undergoing ophthalmic surgery. Fifty patients were divided into Group E (Endotracheal intubation) 25 patients and Group I (I-gel insertion) 25 patients. Ethical committee approval and informed consent from parents/relatives were obtained.

Inclusion criteria: Children between the age of 3-10 years, both sex, ASA physical status I and II, weight between 10-30 kg, and patients between the duration of surgery 30-60 minutes were included.

Exclusion criteria: Patients with glaucoma, a history of intraocular surgery, heart and lung disease, diabetes, BMI > 3kg/m<sup>3</sup>, anatomical defect in mouth and larynx, and airway obstruction were excluded.

Baseline HR, SBP, DBP, MAP, SPO<sub>2</sub>, and baseline IOP for both eyes were recorded in the preoperative period. General anaesthesia was given to the patients via Endotracheal Intubation and I-gel insertion. The hemodynamic parameters like blood pressure, heart rate, and oxygen saturation were measured and compared at five intervals at T0 (baseline), T1 (after the first injection of the anaesthetic drug), T2 (immediately after insertion of the airway device- endotracheal tube or i-Gel), T3 (2 minutes after insertion of the airway device) and T4 (5 minutes after insertion of the airway device). The requirement of intraocular pressure was measured in the post-operative period. The surgery was done, and the patients were shifted to the recovery room. Any incidence of post-operative nausea and vomiting was recorded.

### Statistical Methods

All statistical analyses were done using SPSS version 21.0. The data were expressed as mean and standard deviation, and for quantitative variants, an independent t-test was used for comparison. Similarly, the chi-square and Fisher's exact tests were used to compare qualitative variants. A p-value of < 0.05 was considered statistically significant.

## RESULTS

Of the 50 patients, 31 were male, and 19 were female. Among the 25 patients in Group E, 68% were male, and 32% were female; in Group I, 56% were male, and 44% were female. Their distribution was similar in both groups and was not statistically significant (p=0.382).

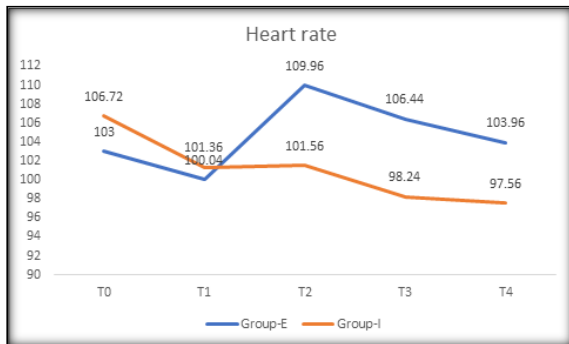
**Table 1: Patient characteristics between the groups**

		Group-E	Group-I	P-value
Gender	Male	17 (68%)	14 (56%)	0.382
	Female	8 (32%)	11 (44%)	
Age (Years)		6.56 ± 3.73	6.12 ± 2.6	0.63
Weight (Kg)		18.44 ± 7.2	16.2 ± 4.67	0.198

IOP (mmHg)	Pre-op	15.64 ± 3.91	14.56 ± 2.86	0.27
	Post-op	11.32 ± 2.85	9.72 ± 2.28	0.022

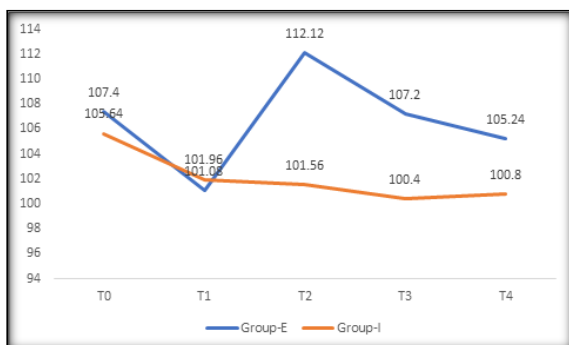
The age distribution in Group E was from 2 years to 13 years, and in Group I was two years to 12 years. The mean age and distribution (6.56 ± 3.73 years in Group E; 6.12 ± 2.60 years in Group I) were similar and were not statistically significant (p=0.63). The mean weight and distribution (18.44 ± 7.2 kgs in Group E; 16.2 ± 4.76 kgs in Group I) were similar and were not statistically significant (p=0.198). The preoperative intraocular pressure between the two groups was not statistically significant between the groups. At the same time, there was a statistically significant difference in the post-operative period in the intraocular pressure with a p-value of 0.022. The postoperative IOP in Group E was 11.32 ± 2.52 mmHg; the same was 9.72 ± 2.22 mmHg in Group I [Table 1].

The heart rate between the two groups was statistically significant at T2, T3, and T4 (p=0.039), (p=0.013), and (p=0.05). The mean heart rates in Group E were significantly higher than those in Group I after the advanced airway insertion [Figure 1].



**Figure 1: Heart rate between groups**

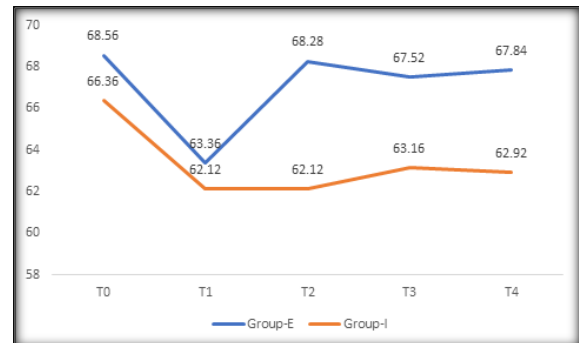
The Systolic blood pressure between the two groups was statistically significant at T2, T3, and T4 (p<0.0001), (p=0.0008), and (p=0.03). The mean Systolic blood pressure in Group E was significantly higher than in Group I after the advanced airway insertion [Figure 2].



**Figure 2: Systolic blood pressure between groups**

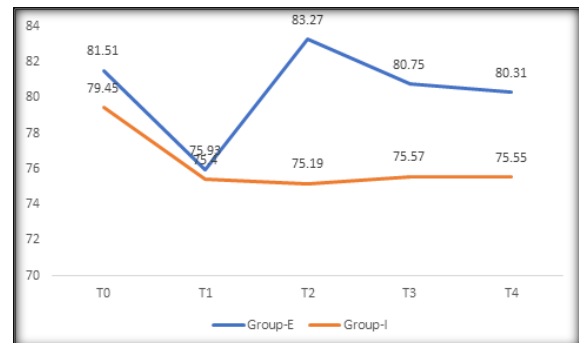
The diastolic blood pressure between the two groups was statistically significant at T2, T3, and T4 (p=0.0006), (p=0.010), and (p=0.002). The mean

diastolic blood pressure in Group E was significantly higher than in Group I after the advanced airway insertion [Figure 3].



**Figure 3: Diastolic blood pressure between groups**

The mean arterial blood pressure between the two groups was statistically significant at T2, T3, and T4 (p<0.0001), (p=0.0022), and (p=0.0019). The mean arterial blood pressure in Group E was significantly higher than in Group I after the advanced airway insertion [Figure 4].



**Figure 4: Mean arterial pressure between groups**

The incidence of PONV in Group E was 24%, while in Group I was 4%. Post-operative nausea and vomiting incidence is statistically significant between the groups (p=0.041). The incidence of PONV was higher after endotracheal tube intubation than I-Gel insertion [Table 2].

**Table 2: Post-operative Nausea and Vomiting (PONV)**

PONV	Group-E	Group-I	P-value
Yes	6 (24%)	1 (4%)	<b>0.041</b>
No	19 (76%)	24 (96%)	

## DISCUSSION

Supraglottic airways are designed to prevent traumatic injuries caused by tracheal intubation. They are inserted into the pharynx to allow ventilation, oxygenation, and administration of anaesthetics as advanced airway devices. I-gel is placed in the hypopharynx instead of insertion into the trachea and causes less stress to the patient. I-gel is used for airway control during spontaneous and

controlled ventilation under general anaesthesia. The insertion of a gastric drain prevents gastric insufflation, which helps decrease nausea and vomiting postoperatively.<sup>[12]</sup> In children, laryngoscopic stimulation may cause laryngospasm or bronchospasm, resulting in serious consequences due to children's low oxygen reserve capacity. Since I-Gel does not involve laryngoscopy, there are fewer chances of laryngospasm or pharyngospasm. Attempts to reduce stress response, IOP and PONV have led to the invention and use of various SADs. The advantages of SAD include lower incidence of hemodynamic changes, PONV, and less rise in IOP when compared with ETT.<sup>[12]</sup>

The baseline values of heart rate, oxygen saturation, Blood pressure (systolic, diastolic and mean arterial pressure), IOP, and PONV were recorded and documented for comparison. It was seen that both the groups were comparable, and there was a statistical difference with a p-value <0.05. The association between the intervention groups in the heart rate changes were analysed with Paired t-test. They were found to be statistically significant with p<0.05 in both groups and also among the groups within the time frame after securing airway devices immediately (T2), 2 minutes (T3), and 5 minutes (T4). Using the I-gel device was not linked to increased hemodynamic variables, including systolic and diastolic blood pressure, MAP, and HR. Still, the LMA and the ETT significantly increased these variables, as was previously documented. In light of this, the I-gel did not affect stress levels in young children having strabismus surgery under general anaesthesia. Our results are consistent with those of numerous other investigations, which all stated that there were no significant changes in hemodynamic variables during the insertion of the I-gel.<sup>[12]</sup>

There was a statistically significant difference in blood pressure between the intervention groups. Intraoperative blood pressure was high in ETT and low in I-gel, and the differences at all the periods (after securing airway devices) were statistically significant with p<0.05 as per paired t-test. There was no statistically significant difference in the oxygen saturation percentage between the intervention groups. The differences at all the periods (after securing airway devices) were not statistically significant, with p >0.05 as per paired t-test. A likely increase in BP and oxygen saturation rates in patients undergoing short surgical procedures using laryngeal mask airway and ETT was reported.<sup>[13]</sup>

The preoperative intraocular pressure between the two groups was not statistically significant between both the comparing groups. At the same time, there was a statistically significant difference in the post-operative period in the intraocular pressure with a p-value of 0.022. The postoperative IOP in Group E was  $11.32 \pm 2.52$  mmHg; the same was  $9.72 \pm 2.22$  mmHg in Group- I. A likely increase in post-operative IOP in patients subjected to ETT than I-gel was reported in patients who underwent elective

eye surgery.<sup>[14]</sup> They also reported significant increases in IOP, 2 and 5 minutes post-exposure to ETT compared to I-gel in all monitored time intervals.

Association between the Group I – I GEL and Group E-ETT groups regarding hemodynamic parameters over varying points of time was assessed using Repeated Measures ANOVA. A statistically significant difference between the two groups was observed in the hemodynamic parameters over time (p<0.05). Our study demonstrated that I-gel usage resulted in less hemodynamic parameter changes compared to tracheal tube and LMA use, but LMA use was linked with improved stability. Our findings concur with those of Watch et al., who found that the ETT group experienced higher alterations in hemodynamic measures.<sup>[15]</sup>

From all the above findings, I -gel has less hemodynamic changes, Post-operative nausea and vomiting (PONV) and less rise in Intraocular pressure (IOP) than Endotracheal intubation. A related study discovered that while using the I-gel approach as opposed to the LMA method, nausea and vomiting were more common and less air entered the stomach.<sup>[16]</sup> Because the i-gel device applies less pressure to the soft tissues of the pharynx than ETT, it may have a less dramatic impact on IOP and pressure responses. Our findings support prior research that inserting the i-gel device caused less cardiovascular reactions than inserting the LMA.<sup>[17]</sup> I-gel does not require inflation once in the airway tract since it features a flexible, gel-like anatomical cuff composed of thermoplastic elastomer.<sup>[18]</sup> By doing so, the sympathoadrenal axis may not be stimulated, preventing an increase in IOP.<sup>[19]</sup> I-gel was shown to be superior to the other two airway devices in maintaining stable hemodynamics and was not linked to an increase in IOP while under general anaesthesia, according to the hemodynamic and IOP response to the insertion of ETT and I-gel.

## CONCLUSION

Our study shows that hemodynamic stress response and IOP raises are significantly higher after insertion as well as after removal of an endotracheal tube than after insertion and removal of I-gel in paediatric ophthalmic surgery patients. I-gel provides a good alternative for airway maintenance in general anaesthesia for selective paediatric ophthalmic surgery patients in whom pressure response to tracheal intubation is detrimental and must be avoided.

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