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COMPARISION OF I-GEL VERSUS ENDOTRACHEAL TUBE IN PAEDAITRIC PATIENTS UNDERGOING DAYCARE OPHTHALMIC SURGERIES

Anesthesiology

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ABSTRACT

INTRODUCTION Most ophthalmic surgeries in children are performed under general anesthesia. Endotracheal intubation and Supraglottic airway devices are the methods used for managing the airway. SAD's like I-gel offer distinct advantages over the ETT in terms of increased speed and reliability of placement, maintaining haemodynamic stability during induction and emergence. It also decreases the incidence of postoperative sore throat (POST). Present study was conducted to compare the use of I-gel and endotracheal tube in pediatric patients undergoing ophthalmic surgeries under general anesthesia. **MATERIALS AND METHODS** A prospective randomized, comparative study was performed in 100 pediatric patients who were divided equally in to two groups of 50 each. Group- E: Airway was secured with endotracheal tube and in Group -I: Airway was secured with I-gel. The devices were compared with regard to 1)Cough response during extubation, 2)Hemodynamic parameters during induction, intraop, extubation post extubation, and 3)post-operative sore throat. **RESULTS** There was significant Increase in mean heart rate, systolic BP and diastolic BP from baseline in Group E(ETT) as compared with Group I(I-GEL) at the time of intubation,5 and 10minutes after intubation, during extubation, 1 and 5 minutes post extubation. Cough severity was significantly less after extubation in Group I as compared with Group E. **CONCLUSION** We conclude that I-gel has a better profile in terms of less hemodynamic changes during intubation, intraop and extubation, with reduced cough severity in post-operative period. Thus, I-gel provides a good alternative for airway maintenance in general anesthesia for pediatric patients in ophthalmic surgeries.

KEYWORDS

I-GEL, Pediatric, ophthalmic surgeries, Endotracheal tube.

INTRODUCTION

Endotracheal tube (ETT) is the gold standard device to secure airway in patients undergoing general anaesthesia (GA). However, over a period of time, new airway devices have been added to the anaesthesiologist's armamentarium.

Supraglottic airway devices (SAD) may offer distinct advantages over the ETT in terms of increased speed and reliability of placement, maintaining haemodynamic stability during induction and emergence, better oxygenation during emergence.[1,2,3] It also provides increased patient satisfaction by decreasing the incidence of postoperative sore throat (POST).[4,5]

The I-gelTM (Intersurgical, Berkshire, Wokingham, UK) [7] is a novel Supraglottic airway device(SAD) made of a medical grade thermoplastic elastomer. It has a non-inflatable cuff to reduce complications associated with compression trauma and high pressure [7].

I-gel design obviates the need for cuff inflation, has a reduced chance of axial rotation and thus malpositioning and reduced the chances of kinking as compared to ETT. A nasogastric tube can be placed through the gastric port of I-gel thereby avoiding insfflation of stomach and regurgitation of gastric contents.[8]

Furthermore, insertion and maintenance of anesthesia were easier with I-gel when compared with other SAD.[9] The soft cuff of I-gel fits well with patient's airway anatomy and produces very little trauma to the airway.[10]

Studies on Cadaver showed that I-gel effectively conformed to the perilaryngeal anatomy and consistently achieved proper positioning for supraglottic ventilation.[11]

Most ophthalmic surgeries in children are performed under general anesthesia. Endotracheal intubation and SAD are the commonest methods used for managing the airway. Laryngoscopy with endotracheal intubation and SAD insertion both increase Intra ocular pressure(IOP), but there was significantly smaller rise in IOP with SAD, both on placement and removal as compared to endotracheal intubation.[12,13] .

This study was conducted to compare the use of I-gel and endotracheal tube in pediatric patients undergoing daycare ophthalmic surgeries under general anesthesia.

MATERIALS AND METHODS

This is a prospective randomized controlled study of interventional type. Institutional ethical committee approval was obtained before the start of the study. The procedure was explained to the patient/guardian and written informed consent was taken.

Inclusion criteria were Age group between 1 to 12 years of both genders, ASA-PS grade 1,2 and Elective and emergency surgeries under general anaesthesia. Patients with Hemodynamic instability, known h/o reactive airway disease, Anticipated difficult intubation and patients having facial deformities were excluded from the study.

A thorough history was taken and a detailed examination was carried out. Patients were subjected to routine and relevant investigations and kept nil per oral as per ASA guidelines.

A standard anesthesia technique was used. On the day of surgery in the operation theatre, intravenous access was established with 22G/24G cannula. ASA standard monitors were attached and baseline pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure and Spo2 were recorded. Patients were pre-medicated with Inj. Glycopyrrolate 0.004 mg/kg iv, Inj. Ondansetron 0.15 mg/kg iv and Inj. Fentanyl 2 mcg/kg iv. After preoxygenation, Induction was done with Inj.Propofol 2 mg/kg iv and Inj.Succinylcholine 2 mg/kg iv. After induction in Group I (I-gel) - appropriate sized I-gel was inserted according to the manufacturer's instructions and depending on the body weight, and appropriate sized infant feeding tube was inserted through the gastric port of I-gel, and in Group-E (ETT) – patients were intubated with appropriate size cuffed/ uncuffed endotracheal tube.

Anaesthesia was maintained with O2+Sevoflurane+ Inj.Atracurium 0.5 mg/kg iv f/b 0.1mg/kg iv maintenance doses. After surgery with the return of spontaneous respiration, the neuromuscular blockade was reversed with inj. glycopyrrolate 0.008mg/kg iv and inj. neostigmine 0.05mg/kg iv. When the patient was fully awake and all the extubation criteria were met, in Group-E (ETT) - after thorough oral suction, cuff was deflated and ETT was removed and in Group I (I-gel) – I-gel was removed after suctioning through infant feeding tube. Parameters observed and compared were 1)heart rate, systolic BP, diastolic BP, mean BP, SPO2 - During intubation, Intra operative period, Extubation, and 1min,2min,5min,10 min,15min and 20min after extubation

2)Severity of cough:
During extubation, at 1min,2min,5min,10 min,15min and 20min after extubation

Grade -0: No cough
Grade -1: Cough lasting for <15 seconds
Grade -2: Cough lasting for >15 seconds
3)Sore throat
Up to 12hrs post extubation.
Grade- 0: No sore throat at any time since the operation
Grade -1: The patient answered in the affirmative when asked about sore throat(minimal sore throat)
Grade -2: The patient complains of sore throat on his own(moderate sore throat)
Grade -3: The patient is in obvious distress(severe sore throat)

Statistical Analysis Methods:
According to Guerrier et al[14] study, considering the incidence of cough at extubation in ETT group as 33% and in I-Gel group as 5% at 95% confidence interval with 80% power, the sample size is calculated as

$$N= [P_1(1-P_1)+ P_2(1-P_2) / (P_1-P_2)^2]* f(\alpha, \beta)$$

N- Sample size required for each group
α – 0.05 (level of significance)
β – 0.2 (80% power)
P1 (%)-Prevalence of cough in ETT Group
P2 (%)-Prevalence of cough in I-Gel Group

The total sample size is calculated as 75(37 in each group). We took sample size of 100(50 in each group).

All data was entered in MS excel 2017 and analysis was done in 2013 GRAPH PAD SOFTWARE. For qualitative data, Chi-square test was applied and for quantitative data, unpaired t-test was applied to determine the statistical difference between the two groups. P value less than or equal to 0.05 was considered as statistically significant.

RESULTS:
The mean age in Group E was 5.62±3.3years, in group I it was 5.68±3years.

The sex distributions in the groups were 30(60%) male, 20(40%) female in Group E. 28(56%) male, 22(44%) female in group I.

ASA distribution in the groups were 14(28%) ASA 1, 36(72%) ASA 2 in Group E. 17(34%) ASA 1, 33(66%) ASA 2 in group I.

Both groups were comparable on basis of age, sex distribution and ASA grade with P value >0.05.

Cough severity was significantly less at the time of extubation,1min, 2min,5min,10min,15min and 20min after extubation in I gel group as compared to endotracheal group with P<0.05(Table 1).

Severity of sore throat is more in Group E than Group I, at1,2,4,8 and12 hours of extubation but it is not statistically significant. With P value more than 0.05 between the groups.

Table-1

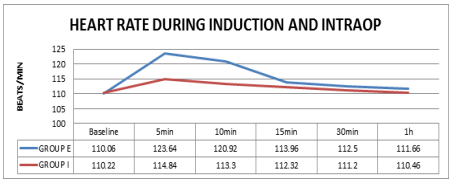
COUGH SEVERITY							
	Time after extubation						
	During extubation	1min	2min	5min	10min	15min	20min
Group E	Grade 0	5	5	5	5	4	29	33
	Grade1	14	15	27	30	45	21	17
	Grade2	31	30	18	15	1	0	0
Group I	Grade0	12	12	13	12	18	45	47
	Grade1	23	5	29	30	32	5	3
	Grade2	15	33	8	8	0	0	0
	P value	0.004	0.01	0.02	0.08	0.002	0.0003	0.0005

The baseline hemodynamic parameters such as heart rate, SBP, DBP, MAP, SPO2 were comparable between the two groups. The P value was > 0.05 and not significant. [Graph-1,2,3,4]

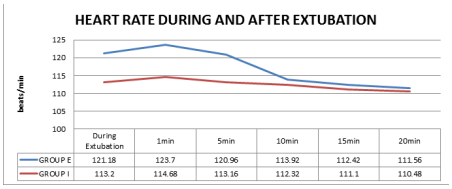
Heart rate, systolic BP, Diastolic BP and mean BP were higher at 5min and 10min after intubation in group E as compared with group I, which was statistically significant with P value less than 0.05.

Heart rate, systolic BP, Diastolic BP and mean BP were higher at extubation, 1min and 5min after extubation in group E as compared to group I, which was statistically significant with P value<0.05.

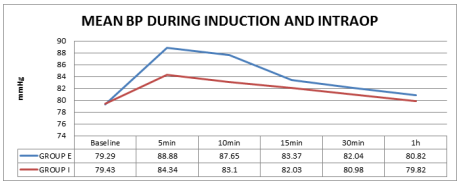
Graph-1



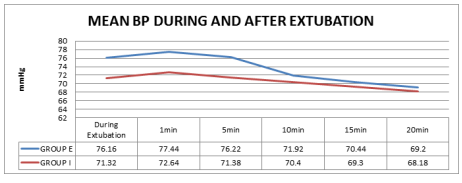
Graph-2



Graph-3



Graph-4



DISCUSSION
Maintenance of a patent airway is essential and vital role of an anesthesiologist and failure to do so, even for a brief period of time, can be life threatening. Pediatric airway is known to be more difficult to manage than adult airway due to anatomical variations.

Endotracheal intubation leads to sympathetic stimulation, hypertension, tachycardia, arrhythmias and in ophthalmic surgeries, rise in intraocular pressure. The Main anesthetic goal in Intraocular surgery is the maintenance of a stable intraocular pressure, as the sudden raise in IOP during open eye surgery can cause prolapse of iris or lens and vitreous loss leading to permanent loss of vision.

There have been enormous efforts implied to reduce the hemodynamic stress response during intubation. Attempts to reduce hemodynamic response have led to invention and use of various SAD.

IGEL, one of the SAD, is being successfully used to maintain airway, the rapid and easy insertion, safety provided by the gastric channel,

decreased rise in IOP, low post operative complications provide benefit to both the surgeon and the pediatric patient.

We undertook this study with primary objective to compare cough severity with the use of I-gel and endotracheal tube in pediatric patients as well as to asses hemodynamic alterations and post operative sore throat.

Study by Guerrier et al[14] evaluated cough severity and post extubation cough between endotracheal group and LMA group, they found significantly greater incidence of coughing at extubation and/or after extubation in the tracheal group than in the laryngeal mask group(P-0.001).

Similar results were found in our study where there was a significantly greater incidence of coughing at extubation, and post extubation in the ETT group than in the I-Gel group with p value <0.05. The anesthetic protocol ensured that both groups were extubated at an equivalent depth of anesthesia.

Contrasting results were found in the study by Jeong In Hong et al[16] where they found that the incidences of cough, laryngospasm, and stridor were not significantly different between the two groups. Differences in the results of these studies may be related to the proficiency of the device user and the sample size.

Study by Ila patel et al[15] found a significant increase in the heart rate and MAP after the insertion of the endotracheal tube compared with the insertion of the I-gel which remained high till 10 minutes after intubation (9% in Group LMA and 11% in Group ETT). They also found a significant increase in the heart rate and MAP after the removal of the endotracheal tube as compared with the removal of the I-gel which remained high till 5 minutes after removal.

From our study we found out that, in both the groups, the mean HR, SBP, DBP and MAP increased after both I-gel as well as Endotracheal tube insertion, but the rise was more in group E at 5min and 10min which was statistically significant(P<0.05). The disparity can be explained by the fact that LMA stimulates both cardiac acceleratory and vagal fibres whereas the cardio acceleratory fibres are much more prominent on endotracheal intubation.[6]

In our study in both the groups, the mean HR, SBP, DBP and MAP increased during removal of airway device, but the rise was more in ETT group, but the difference was statistically significant only at extubation 5min and 10min after extubation. However after 10 mins of extubation or I-Gel removal, the rise was not statistically significant.

Study by Guerrier et al[16] found no significant difference in the incidence of sore throat between I-gel and endotracheal tube. The decreased incidence of sore throat in group I could be due to the fact that mucosal pressures achieved are usually below pharyngeal perfusion pressure.[17]

In our study there was a greater incidence of post operative sore throat after extubation in the ETT group than in the I-Gel group but the increase was not statistically significant. Nevertheless, these cannot be analyzed as the study group is children from 1 to 12 years, and most of them cannot complain of any sore throat reliably.

In our study we did not observe any complications like desaturation(spo2<90%), stridor, bronchospasm, laryngospasm, in both the groups.

From the above findings, we found that I-gel has lesser hemodynamic response and less cough response than ETT.

Our study has few limitations as we have studied pediatric patients, our findings may not be applicable to general population. The severity of sore throat was scored based on patient's subjective assessment which is not reliable in children and we need a better scoring system.

CONCLUSION

To conclude, we observed that I-gel has a better profile in terms of less hemodynamic changes during intubation and extubation, better hemodynamic parameters during surgery, reduced cough severity and less incidence of sore throat in post-operative period. Therefore I- Gel offers a better alternative to endotracheal tube for administration of general anaesthesia in pediatric ophthalmic surgeries. And it is remarkably safe and cost effective.

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