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Comparison of hemodynamic effects with i-gel and endotracheal tube insertion for elective pediatric anesthesia- a prospective study

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ABSTRACT

Background and Aim: Supraglottic airway devices are now widely used for surgery requiring general anesthesia. They provide a perilaryngeal seal with a cuff and an alternative to tracheal intubation. The I-gel is a novel and innovative supraglottic airway management device. Present study was performed to compare hemodynamic effects of I-gel insertion and tracheal intubation in elective pediatric surgical patients.

Methods: A prospective randomized, comparative study was performed in 120 pediatric patients who were divided equally in to two groups (60 each). Group-1 used endotracheal tube and Group-2 used I-gel for airway maintenance. The two devices were compared with regard to the insertion characteristics, hemodynamics and postoperative airway complications.

Results: There was a significant increase in the mean arterial blood pressure after the insertion of the endotracheal tube compared with the insertion of the I-gel. In our study, both the devices were inserted in first attempt in all pediatric patients. So, first time insertion success rate was 100% for both, ETT and I-gel.

Conclusion: The hemodynamic stress response in terms of heart rate, mean blood pressure were significantly higher after insertion as well as after removal of endotracheal tube than after insertion and removal of I-gel in pediatric patients. Thus, I-gel provides a good alternative for airway maintenance in general anesthesia for pediatric patients in whom pressure response to tracheal intubation is detrimental and must be avoided.

Keywords: Endotracheal tube, I-gel, pediatric patients, elective surgery.

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INTRODUCTION

Discovery of endotracheal intubation has not only made administration and maintenance of anesthesia easy, but has also helped in saving several lives. Endotracheal tube intubation is indicated for airway management during general anesthesia, particularly when there is a risk of aspiration. However, it is associated with stress response and is frequently associated with transient hypertension, tachycardia and arrhythmias due to increased catecholamine levels. Supraglottic airway devices (SAD's) mainly consist of different types of laryngeal mask airways (LMA).[1,2] They provide a perilaryngeal seal with a cuff and offer an alternative to tracheal intubation. SAD's are technically easier to insert, allow rapid access to airway, not requiring laryngoscope or muscle relaxant for insertion and are tolerated at lighter anesthetic planes. These may produce less coughing, straining and less pressor response.[3]

I-gel® (Intersurgical™ Ltd., Wokingham, Berkshire, UK) is a novel and innovative SAD, made of a medical grade thermoplastic elastomer, which is soft, gel-like and transparent. It is designed to create a noninflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures. I-gel has been designed as a latex free, single use device. The device has buccal cavity stabilizer which has propensity to adopt its shape to oropharyngeal curvature of the patients.

Insertion of I-gel does not require laryngoscopy, so is not associated with hemodynamic stability.[4,5] The device is very comfortable for children, easy to use for clinicians as well as safe and effective device for use by residents who do not have experience with insertion of a pediatric LMA.[6,7] In our study, we compared pressor responses to insertion and removal of endotracheal tube (ETT) and I-gel. We also measured ease of insertion between the two devices.

METHODOLOGY

This prospective randomized comparative study was carried out at the Anesthesia Department of GMERS Sola Hospital from 01 April 2014 to 01 April 2015 after obtaining approval from the hospital ethics committee and a written informed consent from each patient's guardian. A total of 120 patients undergoing elective procedures were enrolled in the study.

Inclusion criteria were children falling in ASA PS Grade I or II, ages 6-12 y, weighing 16-36 kg, height 90-120 cm, and BMI 20-25 kg/m^2

Patients with any abnormality of the neck movement, mouth opening of ≤ 2 cm, upper respiratory tract infection, history of obstructive sleep apnea or a history of allergy to one or more drugs and latex were excluded.

Patients were randomly divided into two groups of 60 patients each. ETT group received endotracheal intubation and I-gel group received I-gel for airway maintenance in general anesthesia.

All patients were examined to assess their preoperative condition on the day before surgery. Patient's demographic data and history and findings of systemic examination were recorded. Routine investigations ordered included complete blood count, random blood sugar, renal function tests, liver function tests, chest x-ray, and electrocardiography in all patients.

A standardized anesthetic technique was used. Intravenous access was secured and standard monitors attached. All patients were preoygenated with 5-7 L/min for 3-5 min. Patients were given inj fentanyl 2 μg/kg and propofol 2-2.5 mg/kg. After checking for adequate mask ventilation, patients were given succinylcholine 01 mg/kg. Endotracheal tube or I-gel was inserted in respective group patients according to recommended technique. Patients were kept on volume control mode of ventilation with tidal volume 8-10 ml/kg, respiratory rate 12 per min, I:E ratio 1:2 and pressure limit set at 25 cmH_2O.

Patient's hemodynamic parameters MAP and heart rate were recorded just before insertion of the device, and then at 1, 2, 3, 5 and 10 min. Same parameters were recorded just before removal of the device as well as at 1, 2, 3, and 5 min after removal.

Statistical analysis: The data were coded and entered into Microsoft Excel spreadsheet. Statistical analysis was done using the Graphpad Prism version 6.0.7 software (GraphPad Software, Inc. USA). The variables were assessed for normality using the Kolmogorov-Smirnov test. Descriptive statistics were calculated. Means of both groups were compared by independent student t-test. Level of significance was set at $p = 0.05$.

RESULTS

Both groups were comparable in terms of demographic data and there was no significant difference observed between age, height, weight and BMI of the two groups included in our study.

Table 1 shows that heart rate at baseline were comparable between the groups. Heart rate decreased below baseline in both the groups after induction and at 1 min before insertion of endotracheal tube (ETT) or I-gel, which was not statistically significant ($p > 0.05$). There was no statistically significant difference ($p > 0.05$). There was statistically significant ($p < 0.0001$) increase in heart rate after insertion of ETT than after insertion of I-gel.

Table 2 shows that heart rate is comparable at 1 min before removal. Starting from 1 min after removal, even up to 5 min after removal, heart rate is significantly higher ($p < 0.0001$) in ETT group than I-gel group.

Table 3 shows that shows that mean arterial pressure between two groups is

having no significant difference ($p > 0.05$) at baseline and 1 min before insertion of ETT or I-gel. After insertion, there is significant increase ($p < 0.0001$) in mean arterial pressure in ETT group than I-gel group.

Table 4 shows that mean arterial pressure was significantly higher ($p < 0.0001$) in ETT group as compared to I-gel group, before and after removal.

DISCUSSION

The most vital element in providing functional ventilation is the airway, and achieving a safe and effective airway is the principle aim of the anesthesiologist. Management of the airway has come a long way since the development of endotracheal intubation by Macewen[8] in 1880 to the present day usage of sophisticated devices. The tracheal intubation is the gold standard method for maintaining a patent airway during anesthesia. The basic function of a tracheal tube is to provide a reliable connection between the patient's lung and

Table 1: Comparative heart rates (beats/min) on insertion of ETT/I-gel

Time of recording	ETT group	I-gel group	p value
Baseline	90.35 ± 4.950	92 ± 5.399	0.0836
1 min before device insertion	82.72 ± 6.184	82.5 ± 5.815	0.8412
1 min after device insertion	103.13 ± 6.5	85.88 ± 5.609	< 0.0001
2 min after device insertion	103.1 ± 6.183	87.67 ± 6.116	< 0.0001
3 min after device insertion	101.1 ± 6.404	84.63 ± 5.681	< 0.0001
5 min after device insertion	94.35 ± 4.916	81.78 ± 5.518	< 0.0001
10 min after device insertion	85.43 ± 4.942	78.5 ± 5.616	< 0.0001

Statistically significant difference at p = 0.05, Test of significance- Student's t-test

Table 2: Comparative heart rates (beats/min) on removal of ETT/I-gel

Time of recording	ETT group	I-gel group	p-value
Baseline	90.35 ± 4.950	92 ± 5.399	0.0836
1 min before device removal	90.48 ± 5.280	89.45 ± 5.318	0.28
1 min after device removal	98.33 ± 5.850	87.82 ± 5.622	< 0.0001
2 min after device removal	98.72 ± 5.854	86.78 ± 5.527	< 0.0001
3 min after device removal	96.9 ± 5.605	84.58 ± 5.209	< 0.0001
5 min after device removal	88.47 ± 5.363	81.43 ± 5.283	< 0.0001

Statistically significant difference at p = 0.05, Test of significance- Student's t-test

Table 3: Mean arterial pressures (mmHg) at insertion of devices

Time of recording	ETT group	I-gel group	p value
Baseline	77.51 ± 5.410	76.69 ± 5.314	0.4
1 min before device insertion	70.12 ± 5.094	69.033 ± 4.275	0.28
1 min after device insertion	83.21 ± 5.163	71.89 ± 5.102	< 0.0001
2 min after device insertion	86.66 ± 4.878	71.28 ± 4.875	< 0.0001
3 min after device insertion	82.33 ± 4.697	69.31 ± 4.899	< 0.0001
5 min after device insertion	77.67 ± 4.708	67.81 ± 4.995	< 0.0001
10 min after ET/ I-gel insertion	71.48 ± 4.367	65.42 ± 4.318	< 0.0001

Statistically significant difference at p = 0.05, Test of significance- Student's t-test

Table 4: Mean arterial pressures (mmHg) at removal of tube/i-gel

Time of recording	ETT group	I-gel group	p value
Baseline	77.51 ± 5.410	76.69 ± 5.314	0.40
1 min before device removal	86.4 ± 6.0	73.5 ± 5.077	< 0.0001
1 min after device removal	86.47 ± 5.581	75.28 ± 5.115	< 0.0001
2 min after device removal	82.79 ± 5.596	73.99 ± 5.151	< 0.0001
3 min after device removal	79.53 ± 5.465	71.17 ± 4.866	< 0.0001
5 min after device removal	75.77 ± 5.230	68.35 ± 4.619	< 0.0001

Statistically significant difference at p = 0.05, Test of significance- Student's t-test

the bag or ventilator. However, endotracheal intubation in children requires skill and continuous training and practice and usually requires direct laryngoscopy, which may cause laryngopharyngeal lesions.[1] Laryngoscopy and endotracheal intubation produce reflex sympathoadrenal response and are associated with raised levels of plasma catecholamines, hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension.[2,10,11] In children, laryngoscopic stimulation may cause laryngospasm or bronchospasm which may result in serious consequences due to low oxygen reserve capacity of children. Hemodynamic changes at extubation are even higher than during intubation.[12] Being transient, the hemodynamic stress response may probably be of little effect in a healthy individual but it may be severe and more hazardous in patients with compromised cardiovascular system e.g. in hypertension, ischemic heart disease etc. That may cause myocardial ischemia/infarction, left ventricular failure, cerebral hemorrhage and pulmonary edema.

There have been enormous efforts implied to reduce this hemodynamic stress response. Attempts to reduce hemodynamic response have led to invention and use of various SAD's. There are several well-established advantages of using an SAD compared with a tracheal tube. The major ones include lower incidence of sore throat, less hemodynamic derangement during induction and maintenance of anesthesia, better oxygenation during emergence and an increased case turn over. Therefore, recently there has been a trend towards substituting an SAD for a tracheal tube for controlled ventilation in patients with a minimal risk of aspiration.[13]

We undertook a study with a primary objective to compare hemodynamic alteration of endotracheal intubation versus I-gel insertion as well as hemodynamic alteration during ETT removal versus I-gel removal.

The study parameters were significantly increased, after insertion and removal of ETT compared to I-gel.

In our study, both the devices were inserted in first attempt. So, first time insertion success rate for both the devices was 100% in our study.

Ismail SA et al.[14] evaluated intraocular pressure (IOP) and hemodynamic responses following insertion of an I-gel, LMA or endotracheal tube. Tracheal intubation significantly increased HR, SBP and DBP. Insertion of the LMA significantly increased HR and SBP. These increases were significantly higher than those which followed insertion of i-gel. These findings were consistent with our study where I-gel insertion had significantly less ($p < 0.0001$) HR, SBP and DBP than ETT insertion. We did not measure IOP.

Jindal P et al.[15] studied hemodynamic effects of three supraglottic devices: I-gel, SLIPA, and LMA in 75 patients of 20-70 years, and concluded that I-gel effectively conforms to the perilaryngeal anatomy. It consistently achieves proper positioning for supraglottic ventilation and causes less hemodynamic changes as compared to other supraglottic airway devices. We also had similar number of intubation attempts in both groups. Helmy AM et al.[16] showed that number of insertion attempt and hemodynamic status were statistically insignificant between LMA and I-gel. This finding is consistent with our study regarding number of insertion attempts. Uppal V et al.[13] showed no significant difference in terms of success rate of first time insertion between I-gel and LMA-unique.

From all above findings, we found that I-gel has same or lesser hemodynamic response than LMA while LMA has documented lesser pressure response than ETT. However, I-gel causes very less or no hemodynamic stress response than ETT.

Our study has few limitations as we have studied pediatric patients of specific age group, our findings may not be applicable to general population. We have studied hemodynamic response in controlled ventilation. Response in spontaneously ventilated anesthetized patients may differ from our study.

CONCLUSION

The results of our study show that hemodynamic stress response is significantly higher after insertion as well as after removal of endotracheal tube than after insertion and removal of I-gel in pediatric patients. Thus, I-gel provides a good alternative for airway maintenance in general anesthesia for selective pediatric patients in whom pressure response to tracheal intubation is detrimental and must be avoided.

Conflict of interest: None declared by the authors

Authors' contribution:

IP: Study Design, manuscript editing

MM: Drafting of the manuscript, statistical analysis

SP: Data collection

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