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Original Research Article

Comparative Study of Use of I-Gel versus Endotracheal Intubation in Paediatric Patients

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Conflict of interest: Nil

Abstract

Background and Aim: Due to availability of I-gel in different sizes, I-gel has gained increasing popularity as an alternative airway device in paediatric patients which is available in three adult and four paediatric sizes in the range. The depth of the anaesthesia for I-gel insertion is less than that required for endotracheal intubation. Present study is an effort to compare the two devices that is I-gel and Endotracheal Tube in Paediatric Patients.

Material and Methods: The present study was carried out as prospective observational study at the tertiary health centre. A total of 50 patients were included in the study. Pediatric Patients posted for surgery fulfilling Inclusion criteria were randomly divided into 2 groups. Group ETT: Endotracheal intubation (n=25) and Group I-GEL: I-gel insertion (n=25). Various parameters recorded were duration of surgery, duration of anaesthesia, insertion time and number of attempts for insertion of I-gel/ Endotracheal tube, ease of insertion and complications and need for rescue anaesthesia.

Results: In comparison with I-GEL group in patients of endotracheal intubation mean arterial pressure was significantly higher in postoperative period. There is no significant difference in the MAP after 60 min between two groups ($p>0.05$)

Conclusion: I-GEL insertion is easy, requires less time and less attempts to insert as compared to endotracheal intubation. I-GEL insertion is associated with less Haemodynamic changes as compared to Endotracheal intubation. After removal of I-GEL, patient becomes haemodynamically stable earlier than Endotracheal intubation. I-GEL does not cause tracheal stimulation.

Keywords: I-GEL, Endotracheal Intubation, Mean Arterial Pressure, Sore throat.

Introduction

In pediatric anaesthesia, Airway management is an essential skill. Securing an airway is vital task for the anaesthesiologist. As compared to adult, the paediatric patients have significant anatomical and physiological differences so that a challenging airway, inadequately prepared or sub-optimally managed airway can determine morbidity and mortality in these patients [1,2].

I-gel has no cuff mechanism which leads to potential advantages like easier insertion, stability after insertion, minimal tissue compression, simplicity in production process and cheaper in cost. It is not necessary to insert fingers in the mouth of the patient for full insertion [3]. Due to The smoother undersurface of the device it allows the device to easily slide along the back of the throat and secure its place. The I-gel requires lesser amount of technical skill and very little training compared to previous methods because of its simpler design As the device is only intended for single-patient use, there is no sterilization required after use [3,4].

Due to availability of I-gel in different sizes, I-gel has gained increasing popularity as an alternative airway device in paediatric patients which is available in three adult and four paediatric sizes in the range. In pediatric patient, where it is difficult to ventilate during respiratory or cardiac arrest, I-gel offers an effective alternate to endotracheal intubation [5,6].

The depth of the anaesthesia for I-gel insertion is less than that required for endotracheal intubation. I-gel may be inserted immediately after an adequate dose of an intravenous or volatile anesthetic agent. Because of its easier insertion, I-gel has unique advantage in patients with difficult anatomical abnormalities where vocalcords can't be visualized with laryngoscope for intubation [7,8]. I-gel insertion is contraindicated in Obstructive lesions below the glottis. Other contraindications include trismus, limited mouth opening, pharyngo-perilaryngeal abscess, trauma or mass, conscious or semi-conscious patients with an intact gag reflex [9].

Gold standard technique for securing airway is Endotracheal intubation which provides a definitive airway protection against the aspiration of gastric contents and also allows positive pressure ventilation with higher airway pressure than with supraglottic airway device. Endotracheal intubation is facilitated by direct laryngoscopy [10]. In children undergoing intrathoracic, upper abdominal,head and neck surgery and laparoscopic procedure as well as for procedure requiring prone, lateral and sitting position endotracheal intubation is mandatory. Additionally, intubation is also necessary for patients with full stomach [11].

Endotracheal intubation has potential disadvantages which include increased airway resistance when patient is breathing spontaneously; Trauma to larynx and subglottis; possible laryngospasm during both intubation and extubation; damage or dislodged teeth, laceration of soft tissue and haemorrhage in case of nasotracheal intubation, esophageal intubation or endo-bronchial intubation. This study is an effort to compare the two devices, that is I-gel and Endotracheal Tube in relation to attempts of insertion, ease of insertion, mean duration of insertion, hemodynamic response, SpO2 and post operative complications in paediatric patients undergoing general anaesthesia.

Material and Methods

The present study was carried out as prospective observational study after obtaining approval from institutional ethical committee. The written informed consent was taken from parents/guardian of the all included patients. Study was conducted for period of one year and three months which includes twelve months for data collections and three months for data entry data analysis and report

preparation. The study was done at the tertiary health centre. A total of 50 patients were included in the study.

The inclusion and exclusion criteria for the present study were as follows:

Inclusion criteria:

- Age group: 2-8 years
- Children weighing 10 -25 kg
- Physical status**:** ASA I/II
- Type of surgery**:** Elective surgical and orthopaedic Surgeries

Exclusion criteria:

- Difficult intubation
- Patient with Pharyngeal pathology
- Pulmonary disease
- ardiovascular disease

Pediatric Patients posted for surgery fulfilling Inclusion criteria were randomly divided into 2 groups.

1. **Group ETT:** Endotracheal intubation (n=25)

2. Group I-GEL: I-gel insertion (n=25)

The complete medical history of the patient including cough, cold, breathlessness, fever, history of convulsion, cardiac disease, any respiratory disease, mental retardation or delayed milestones were recorded in the parforma. Physical examination including airway assessment was done.. Basic hematological and laboratory investigations like complete blood count, blood sugar, bleeding time, clotting time were reviewed.

We confirmed that all the patients were nil by mouth for 6 hours prior to anaesthesia. On the day of surgery we gave syrup Midazolam (0.5 mg/kg) orally to all the patients as premedication. After 45 min we secured I.V line through which Inj. Glycopyrrolate (0.004 mg/kg) and Inj. Ondansetrone (0.1 mg/kg) were given intravenously. After it we started Inj.Isolyte-P 8-10 ml/Kg/hr. We recorded pre-operative pulse and blood pressure in operation room.

All the patients were pre-oxygenated with 100% Oxygen for 3 minutes with face mask. Induction of anaesthesia was done with Inj. Propofol (2 mg/kg) I.V. mixed with Inj. lignocaine 0.5 mg/kg I.V. and Inj. Atracurium was used as neuromuscular blocking agent in loading dose of 0.5 mg/kg and maintenance dose of 0.1 mg/kg I.V. given as required. Inj. Pentazocine 0.5mg/kg was given for post operative analgesia.

In group ETT(Endotracheal intubation), Laryngoscopy and endotracheal intubation was done with appropriate size endotracheal tube. In group I-GEL, I-gel size 1.5 - 2 was inserted. Before insertion posterior surface of I-gel was well lubricated with 2% lignocaine jelly. The position of endotracheal tube or I-gel was checked by observing bilateral chest movement and auscultation for breath sound during controlled ventilation.

Anaesthesia was maintained with O2 (50%), N2O (50%), Sevoflurane and positive pressure ventilation. Pulse, Systolic blood pressure, Diastolic blood pressure, Mean arterial pressure, and SpO2 were monitored before induction, intra-operative and post-operative period.

In this study we recorded the duration of surgery, duration of anaesthesia, insertion time and number of attempts for insertion of I-gel/ Endotracheal tube, ease of insertion any complications like aspiration, bronchospasm, laryngospasm, blood on the surface of airway device, sore throat, hoarseness of voice etc. and need for rescue anaesthesia. We allowed maximum three attempts for insertion of airway device. We assessed ease of insertion as easy as successful at first attempt, Difficult as successful but with some difficulty for some reason and Impossible as not successful.

Reversal of anaesthesia was done by Injection Neostigmine 0.04mg/kg I.V. and Injection Glycopyrrolate 0.008 mg/kg I.V. Airway device was removed after proper oral suctioning. Patients were monitored for any postoperative complications like blood on

surface of I-gel/ ET tube, aspiration, sore throat, hoarseness of voice, laryngospasm, bronchospasm.

When patients were fully conscious, they were shifted to recovery room. Pulse, Systolic blood pressure, Diastolic blood pressure, Mean arterial pressure, SpO2 were monitored about 120 minutes postoperatively.

The incidence of complications like blood on the surface of I-gel/ ET (endotracheal tube) was significantly higher-16% in endotracheal intubation as compared to I-gel insertion-8% ($p<0.05$). Postoperative sore throat was recorded in 16% patients of endotracheal intubation and 20% patients of endotracheal intubation complained of hoarseness of voice. 8% patients of ETT (endotracheal intubation) group developed bronchospasm in postoperative period. No patient in I-gel group developed postoperative sore throat, hoarseness of voice and bronchospasm. No incidence of aspiration or laryngospasm was recorded in any patient. The incidence of fall in SpO2 was not recorded in any patient at different time interval. No any patient needed rescue anaesthesia.

Results

After approval from institutional ethical committee, 50 paediatric patients scheduled for surgical or orthopaedic surgery of ASA- I and II between age group of 2-8 years of either sex were included in this study.

All Patients were given oral Midazolam (0.5mg/kg) before 45 minutes and premedicated with inj. Glycopyrrolate 0.004 mg/kg intravenously, inj. Ondansetron 100 µg/kg intravenously.

Patients were divided into following 2 groups:

Group ETT (n=25) = Endotracheal Intubation

Group I-GEL (n=25) = I-gel insertion

In Group ETT, all patients were intubated with appropriate size of endotracheal tube.

In Group I-GEL, I-gel was inserted.

Vital parameters like pulse rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial pressure,SpO2 were monitored before induction, intra-operatively and postoperatively.

Insertion time for endotracheal tube and I-gel was recorded. Complications like blood on the surface of I-gel/ Endotracheal tube, sore throat, hoarseness of voice, aspiration, laryngospasm and bronchospasm were recorded.

The statistical analysis was done by chi -square test and independent t- test for inter group comparison with the usage of EPI software.

Formulation of Hypothesis:

Null Hypothesis: H0 = There is no difference in the various parameters when both groups compared.

Alternate Hypothesis Ha= There is difference in the various parameters when both groups compared. P value < 0.05 is considered as statistically significant.

If p value < 0.05 we can reject the null hypothesis and consider the alternate hypothesis. Patients were distributed equally in both the groups, 25 patients in each group. In ETT group the mean age was 5.44 ± 2.162 years and the mean weight was 14.52 ± 3.22 kg. In ETT group 80% patients were male and 20% patients were female. In I-gel group the mean age was 5.44 ± 2.142 years and the mean weight was 13.92 ± 3.32 kg. In group I-gel 84% paediatric patient were male and 16% paediatric patients were female. The difference in the demographic data was clinically insignificant ($p>0.05$). Thus both the groups were comparable to each other in demographic data.

In ETT (endotracheal itntubation) group, mean duration of Surgery was 79.8 ± 4.44 minutes and mean duration of anaesthesia was 90.00 ± 4.787 min. In I-GEL group, mean duration of surgery was 80.6 ± 4.16 minutes and mean duration of anaesthesia was 88.20 ± 5.568 minutes. From this we can conclude that the

difference between mean duration of surgery and mean duration of anaesthesia between two group is insignificant

In ETT group, endotracheal intubation was done in all the patients. It was easy in 64 % of the patients and difficult in 36 % of the patients. In I-GEL group, I-gel was inserted in all the patients. I-GEL insertion was easy in 92% of the patients and difficult in 8% patient. Table 3 shows that there is a significant difference in ease of insertion between two groups (P<0.05)

Mean Arterial Pressure (MAP) at different time intervals postoperatively. Patient's mean arterial pressure was recorded at 15 min, 30 min, 45 min, 60 min, 90 min and 120 min in

postoperative period.

In group ETT (endotracheal intubation), mean arterial pressure was 88.56±5.11, 86.80±5.03, 84.86±5.03, 82.99±4.88, 82.77±4.83 and 82.61±4.84 at 15 min, 30 min, 45 min, 60 min, 90 min and 120 min respectively in postoperative period. In group I-GEL, mean arterial pressure was 83.36±5.42, 82.21±4.90, 81.57±4.94, 81.20±4.82, 81.01±4.88 and 80.91±4.79 at 15 min, 30 min, 45 min, 60 min, 90 min and 120 min respectively in postoperative period.

In comparison with I-GEL group in patients of endotracheal intubation mean arterial pressure was significantly higher in postoperative period ($p< 0.001$ at 15 min time interval; $p<0.05$ at 30 min and 45 min time interval). There is no significant difference in the MAP after 60 min between two groups ($p>0.05$)

Table 1: Ease of insertion

Ease of insertion	ETT	I-GEL
Easy	16	23
Difficult	09	02
Impossible	00	00

Table 2: Complications encountered in study

Complications	Group – ETT	Group - IGEL
Blood on Surface of I-GEL/ET tube	16%	8%
Aspiration	0	0
Sore throat	16%	0
Hoarseness of voice	20%	0
Laryngospasm	0%	0
Bronchospasm	8%	0

Discussion

To maintain airway patency and ensuring adequate ventilation and oxygenation is one of the fundamental responsibilities of an Anaesthesiologist. Management of the airway has come a long way since the development of endotracheal intubation by macewe in 1880 to the present day of sophisticated devices [12-14]. Anaesthesia in children was made possible by the invention of endotracheal tube, to which lengthy and complex surgical procedures made feasible without the disastrous complications of airway obstruction, aspiration of gastric contents or asphyxia Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised level of plasma catecholamines, hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension. The present study was undertaken to evaluate the usage of I-GEL in children and it was

compared with Endotracheal Intubation [14,15].

Total 50 patients of 2 to 8 years of age and ASA- I and II scheduled for Surgical and orthopedic surgeries under general anaesthesia were enrolled in this study and randomly allocated in two groups of 25 patients each.

All patients were premeditated with oral Midazolam and Inj. Glycopyrrolate. Induction of anaesthesia was done with Inj. Propofol and Inj. Atracurium and maintained with Oxygen, Nitrous oxide, Sevoflurane and Inj. Atracurium.

Patients were divided into following 2 groups:

Group ETT (n=25) – Endotracheal intubation

Group I-GEL (n=25) – I-gel insertion

In group ETT, Laryngoscopy and endotracheal intubation was done with appropriate size endotracheal tube.

In group I-GEL, I-gel was inserted.

After completion of surgery the effect of neuromuscular blocking agent was reversed with Inj. Glycopyrrolate and Inj. Neostigmine.

Duration of surgery, duration of anaesthesia, insertion time and No. of attempts (Maximum 3 attempts) for insertion of I-gel/ Endotracheal tube, ease of insertion, any complications like aspiration, bronchospasm, laryngospasm, blood on the surface of airway device, sore throat, hoarseness of voice etc. and need for rescue anaesthesia were recorded.

We recorded the ease of insertion of endotracheal tube and I-gel in this study. Table 3 shows the ease of insertion of airway device in two groups. In ETT group, endotracheal intubation was done in all the patients. It was easy in 64 % of the patients and difficult in 36 % of the patients. In I-GEL group, I-gel was inserted in all the patients. I-GEL insertion was easy in 92% of the patients and difficult in 8% patient. It shows that there is a significant difference in ease of insertion between two groups ($P<0.05$).

Ankur dhandha at el (2017) assessed ease of insertion of I-gel and endotracheal intubation in their study they observed that I-gel was easier in (96.67%) to insert as compared to an endotracheal intubation (73.33%).This study is comparable with our study [16].

Tandale Sushma Raghunath at *et al* (2015) [17] did evaluation of I-gel in children undergoing day care procedure .In her study she observed that 119 out of 120 patients ,I-gel was easily inserted without any difficulties .This study is comparable with our study.

In our study we recorded the number of attempts required to insert the endotracheal intubation or I-gel. In group ETT (endotracheal intubation), 64 % of the patients were intubated in first attempt, 32% of the patients required second attempt for intubation and in 4% of the patients, more than two attempts were done for intubation. In I-GEL group, I-gel was inserted in first attempt in 92% of the patients and only 8% of the patients required second attempt and none required more than 2 attempts. So, from this table we can say that number of attempts require for I-GEL insertion is significantly lower than endotracheal intubation ($p<0.05$). Ankur dhandha *et al* (2017) observed that there was no significant difference in number of attempts between I-gel and endotracheal intubation. Our study is in contrast with this study

Meghakohli *et al* (2019) observed that the first attempt success rate for insertion of endotracheal tube and I-gel was 97.5% and 77.5%.our study is in contrast with this study [18].

We recorded the insertion time for endotracheal tube or I-gel in our study. Table 5 shows the difference between “Insertion Time” of airway device (ET tube/I-gel) between the groups. Insertion time is defined as the time from removal of the face mask to connection of anaesthetic gas circuit to the airway device. In I-GEL group , insertion time was 16.52 ± 2.12 seconds which is significantly lower than

ETT(endotracheal intubation) group 25.52 ± 4.11 seconds ($p<0.05$).

Ankur dhamdha *et al* (2017) observed in their study that time needed to insert endotracheal tube (16.67±2.87 seconds) is greater than the time needed to insert the I-gel (10.03±2.01 seconds) ($p=0.001$). This study is comparable with our study.

Samia M. massoud *et al* (2014) observed that there was significant difference between I-gel and endotracheal tube for time of insertion ($p=0.0029$). This study is comparable with our study.

We observed that 16 % of the patients from group ETT and 8% patients from group I-GEL had blood on the surface of airway device after extubation. The incidence of blood on the surface of ET tube was significantly higher than I-GEL ($p<0.05$). In group ETT (endotracheal intubation), there were higher incidence of postoperative sore throat (16%), hoarseness of voice (20%) and bronchospasm (8%).

In group I-GEL no patient developed incidence of postoperative sore throat, hoarseness of voice and bronchospasm. No patient in our study developed laryngospasm or aspiration and no patient required rescue anaesthesia. There was no significant decrease in SpO2 level in any patient in our study.

Conclusion

I-GEL insertion is easy, requires less time and less attempts to insert as compared to endotracheal intubation. I-GEL insertion is associated with less Haemodynamic changes as compared to Endotracheal intubation. After removal of I-GEL, patient becomes haemodynamically stable earlier than Endotracheal intubation. I-GEL does not cause tracheal stimulation. Intra operative and post operative Complications are less in I-GEL compared to endotracheal intubation. Hence, use of I-GEL in positive pressure ventilation is a better alternative to Endotracheal intubation in children.

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