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Research Article

Comparative Evaluation of I-Gel with Uncuffed Endotracheal Tube for Adequacy of Ventilation in Elective Paediatric Surgeries

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ABSTRACT

Background: Uncuffed endotracheal tubes (ETTs) are standard of care for airway management in children up to eight years of age. Direct Laryngoscopy and endotracheal intubation are invasive techniques which may cause hemodynamic changes and can give rise to airway complication. Supraglottic airway devices have been introduced since the past few decades for the management of airway in both adults and children. I-Gel, a second generation supraglottic airway device, is used frequently for securing airway for children.

Methods: Total of 90 children of age 2-8 years of age were randomized into two groups, 45 children were ventilated with I-Gel and remaining 45 were ventilated with an uncuffed ETT. Ventilatory parameters like oropharyngeal leak, peak airway pressure and airway sealing quality (ASQ) score were monitored intraoperatively and possible complications were observed at a timely interval after removal of device.

Results: Mean oropharyngeal leak pressure in the I-Gel and uncuffed ETT group observed were 20 cmH2O and 19.56 cmH2O respectively. ASQ score was comparable in both groups. Ten patients in the I-Gel group while two in the uncuffed ETT group had blood staining of the device after removal and the difference was statistically significant. Incidence of cough and sore throat post-extubation and after six hours was significantly higher in the ETT group as compared to the I-Gel group.

Conclusion: Both devices were comparable and equally effective for adequacy of ventilation while blood staining of the device was observed in the I-Gel group however, cough and sore throat were observed in the ETT group.

Introduction

Airway management and adequate ventilation are the important aspects of anaesthesia. The endotracheal tube is the proven standard of care for airway management. In children, up to eight years of age uncuffed endotracheal tube is preferred [1]. Peculiar features of pediatric airway anatomy is a special concern and can be challenging for securing definitive airway in this age group as compared to adult airway [2].

After years of constant research, the first supraglottic airway device was introduced in 1981. With the availability of supraglottic airway devices(SAD), studies have been done comparing them with endotracheal tube (ETT).

I-Gel (i-gel, Intersurgical Ltd., UK) is a single-use second-generation SAD made of a medical-quality thermoplastic elastomer. Soft non-inflatable cushion like cuff mimics the shape of larynx and have advantage of less pressure and trauma on laryngeal mucosa.

Unique design of I-Gel with firm inbuilt bite block and separate channel for gastric tube which prevents insufflation of stomach making it more safe during controlled ventilation. [3]. Compared to older SADs, I-Gel have better sealing quality, higher oropharyngeal

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leak pressure (OLP) and easier to insert [4].]. Paediatric I-Gel first became available in March 2009 and was officially launched for use in January 2010 [5]. Direct Laryngoscopy and Endotracheal intubation are invasive techniques that cause hemodynamic alteration and can also give rise to airway complications such as dental injury, trauma to vocal cords, airway edema which can be life threatening in paediatric patients [6].

Very few studies are reported in literature comparing I-Gel with uncuffed endotracheal tube in paediatric patients. So, we compared I-Gel with uncuffed endotracheal tube for adequacy of ventilation and post-operative complications in paediatric patients.

Methods

After Institutional Ethical Committee approval and obtaining parents or guardians written informed consent in the language they understood, we conducted a prospective randomized controlled study in a tertiary care hospital over duration of 2019-2021.

Children between the ages 2-8 years, weighing 10-30kgs, belonging to ASA I, II posted for elective surgery of duration less than 2 hours were included in the study. Children with known or predicted difficult airway, pathology of neck or respiratory tract were excluded from the study.

Sample size was calculated based on the standard deviation from previous study [6] keeping power at 80% and confidence intervals at 95% (Type I/ alpha error at 0.05%), a sample of 90 patients would be required. They were randomly divided into two groups, group I – ventilated with I-Gel and group E ventilated with uncuffed endotracheal tube as shown in Figure 1 by computer generated random numbers.

All children were evaluated pre-operatively and standard nil per oral guidelines [7] were followed. All patients were pre-medicated with IV Glycopyrrolate 0.04mg/kg and IV fentanyl 2 mcg/kg. General anaesthesia induced with IV Propofol 2mg/kg and IV Atracurium 0.5mg/kg. I-Gel was inserted in group I, and uncuffed endotracheal tube of appropriate size was inserted in group E. Successful insertion and ventilation were confirmed by capnography and bilateral chest movements on gentle manual ventilation, air entry on both sides was auscultated by a stethoscope for both the devices. Ryle's tube was inserted in both the groups. It was decided to withdraw patients from the study after a second failed insertion attempt and it was recorded as failed insertion and excluded from further statistical analysis.

With a fixed gas flow rate of 3L/min and closing the expiratory valve of the circle system, airway pressure at which noise of leak was heard by placing the stethoscope lateral to the thyroid cartilage is taken as oropharyngeal leak pressure.

For maintaining depth of anaesthesia 1 Lit/min of oxygen, 1 Lit/min of air and inhalational agent Sevoflurane (MAC 1) was used. Vital parameters like pulse rate, systolic, and diastolic blood pressure and ventilatory parameters like end-tidal carbon dioxide, inspiratory tidal volume, expiratory tidal volume, and peak airway pressure were noted at baseline and every 15 minutes till the end of surgery. Tidal volume loss was calculated by subtracting expiratory volume from inspiratory volume observed on the ventilator display screen of the workstation. From this tidal volume leak percentage and ASQ score were calculated.

- Airway Sealing Quality Score (ASQ) [8]

1 - No leak detected,
2 - Minor leak of TV (TV leak < 20%),
3 - Moderate leak of TV (TV leak – 20% to 40%),
4 - Insufficient seal (TV leak > 40%).

After closure of skin, sevoflurane switched off and on fulfilling clinical criteria to reverse neuromuscular blockade, Neostigmine 0.05mg/kg with Glycopyrrolate 0.1 mg /kg given intravenously and device was removed. Immediately after extubation, blood staining of the device, laryngospasm, aspiration in Ryle's tube, and stridor if any was noted. Postoperative complications in the form of cough, sore throat were assessed immediately after regaining full consciousness and after 6 hours.

Statistical Analysis

Chi-Square test was used for inter-group statistical comparison of the distribution of categorical variables. Independent sample t-test was used for inter-group statistical comparison of means of normally distributed continuous variables and for non-normally distributed variable Mann-Whitney U test was used. P-values less than 0.05 were considered statistically significant. Entire data was analyzed using using SPSS, version 22.0 (SPSS version 22.0, IBM Corporation, USA).

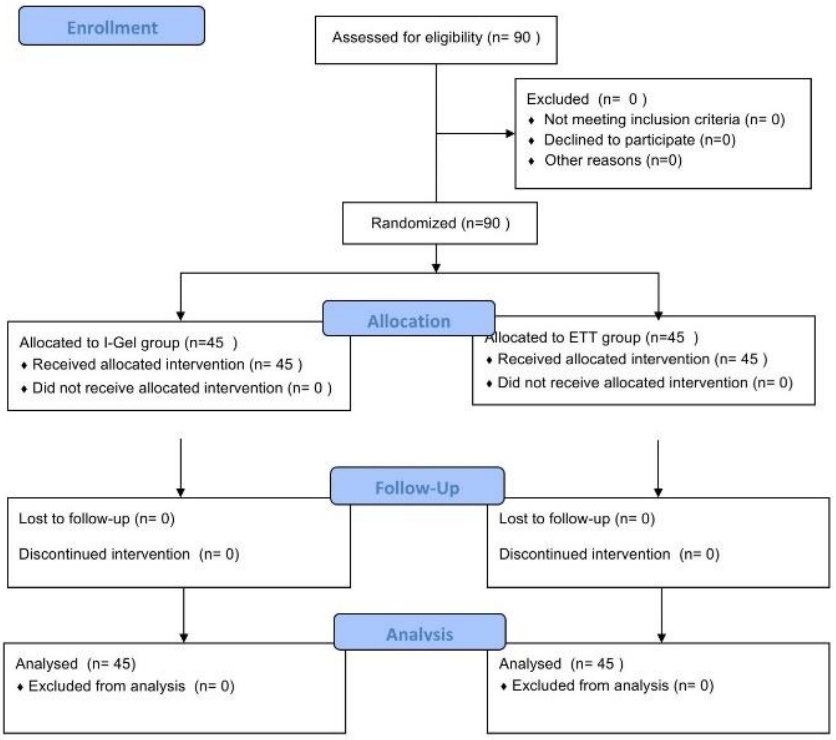

Figure 1- Consort flow diagram

Results

We conducted a prospective randomized controlled study to compare 90 paediatric patients planned for elective surgery under general anaesthesia who were ventilated either by I-Gel or by uncuffed endotracheal tube.

The demographic parameters such as age, gender, body weight, and ASA were statistically comparable in both the groups as shown in (Table 1).

Table 1 – Demographic Data

Parameter	Group I	Group E	P Value
Age (years)	4.48 ± 2.13	4.41 ± 1.86	0.874
Gender -Male (n) -Female	40 05	39 06	0.748
Weight (kg)	14.70 ± 4.35	15.20 ± 4.37	0.591
ASA – Grade I Grade II	31 14	28 17	0.506

Hemodynamic responses such as pulse rate and mean arterial blood pressure were similar in both the groups. No significant difference was observed in the end-tidal carbon dioxide and saturation at timely intervals in either of the groups.

(Table 2) shows mean oropharyngeal leak pressure in the I-Gel group was 20cmH2O whereas in the uncuffed endotracheal tube group it was 19.56cmH2O which was comparable and non- significant.

Table 2 – Mean oropharyngeal leak pressure

Parameter	Group I (n = 45)	Group E (n = 45)	P Value
Mean OPL Pressure (cm of H2O)	20.00 ± 1.73	19.56 ± 0.97	0.136

Adequacy of ventilation was assessed by measuring airway sealing quality (ASQ) score at intervals of 15 minutes from baseline till the end of surgery as shown in (Figure 2). ASQ score was comparable and statistically insignificant between both the groups. Along with this peak airway pressure in either of the groups did not show any significant difference.

Ten patients in the I-Gel group and two patients in the uncuffed endotracheal tube group had blood staining of the device after removal, (P= 0.027). Statistically significant difference was not seen on comparing side effects like laryngospasm, aspirate in Ryle's tube, and stridor as shown in (Figure 3).

As shown in (Figure 4), the incidence of cough post-extubation and after 6 hours in the uncuffed endotracheal tube group was 17.8% and 15.6% respectively while in the I-Gel group it was 2.2% and 0% and this difference was statistically significant (post extubation: P= 0.030, after 6 hrs: P= 0.012). Similarly, the incidence of sore throat in the uncuffed endotracheal tube group after

extubation was 20% and after 6 hours was 17.8% as compared to 2.2% after extubation and 0% after 6 hours in the I-Gel group. These findings were statistically significant (post extubation P= 0.015, after 6 hrs P 0.006).

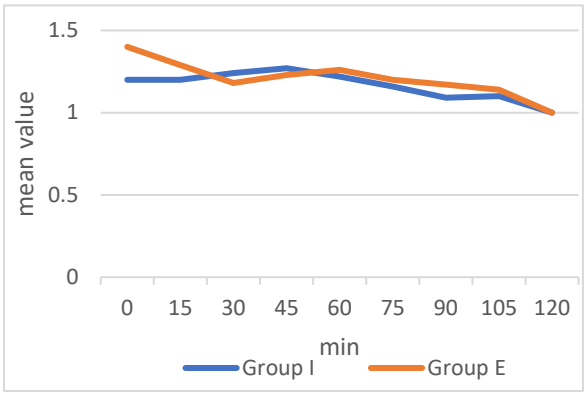

Figure 2- Mean airway sealing quality score

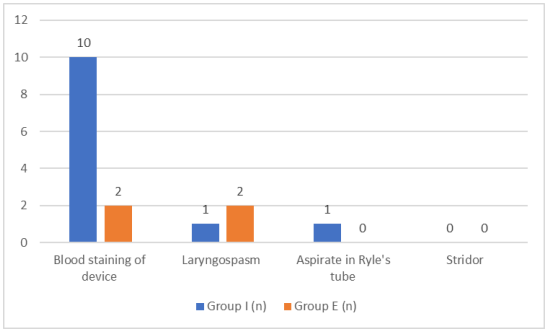

Figure 3- Post operative events:

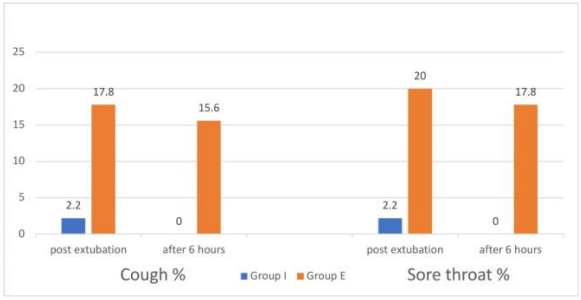

Figure 4- Postoperative complications

Discussion

Securing the airway is a crucial task, to a greater extent a paediatric airway. Understanding paediatric airway anatomy and physiology is very important for an anaesthesiologist. Initially, there were two methods of maintaining the airway, either endotracheal tube or facemask. Uncuffed endotracheal tubes have been the most preferred method for securing the airway in children till eight years of age [1]. With the invention of supraglottic airway devices like I-gel, it became an alternative method of maintaining airway.

We compared 90 children randomly assigned into either I-Gel or Uncuffed ETT group to check adequacy of ventilation and any post-operative events.

Demographic data and intraoperative hemodynamic variables between both groups were comparable and statistically insignificant. On contrary, study conducted by Sindhura and Sowbhgyalakshmi found increase in mean arterial pressure in ETT group as compared to i-gel group in first five minutes of insertion [9].

Monitoring of respiratory rate, oxygen saturation (SpO2) and end-tidal carbon dioxide (EtCO2) between both groups was done throughout the surgery and no significant statistical difference between the two groups was seen. Kohli M et al [6] in 2019, in their study between I-Gel and ETT in laparoscopic surgeries, they observed a significant rise in end-tidal carbon dioxide after carboperitoneum in both groups. Since there was not any laparoscopic surgery in our study, we did not observe any such rise in end-tidal carbon dioxide.

Oropharyngeal leak pressure between the two groups was similar and did not differ statistically. Lee et al also found similar results while comparing i-gel and LMA Classic in 99 children [10]. These findings can be explained by more compliant tissue in paediatric age group.

Adequacy of ventilation was observed by measuring inspiratory tidal volume (TVi), expiratory tidal volume (TVe), and tidal volume leak (TVl). With the help of this data, we calculated the leak percentage and airway sealing quality score (ASQ). Our findings did not show any significant difference in ASQ score between the two groups. Because of the thermoplastic properties of I-Gel after coming in contact with the core temperature of the body, the non-inflatable cuff of I-Gel forms a good seal around the larynx preventing any loss of tidal volume. A study done by Chauhan G et al [8] comparing I-Gel with proseal LMA in adults reported no major loss of tidal volume (i.e., > 40%) between both the groups. They observed ASQ scores of 1 in 80% of patients and ASQ score 2 in 20% of patients in both groups which were comparable and not significant. We did not come across any references or studies in the literature comparing airway sealing quality score in paediatric age group.

Hong JI et al [11] comparing clinical performance of I-Gel and ETT in paediatric laparoscopic surgeries, reported consistently high peak airway pressure with endotracheal tube compared to the I-Gel group which was statistically significant. This could be due to the insufflation of the peritoneum with carbon dioxide. We did not observe any such findings with either of the groups in our study and peak airway pressures were statistically similar in both groups. Radhika KS et al in their study comparing i-gel and LMA supreme for efficacy of ventilation in terms of laryngeal sealing pressure, leak fraction and peak inspiratory pressure and

found both devices suitable for positive pressure ventilation [12].

Blood staining of the device after removal was seen in ten children (22.2%) in the I-Gel group and two children in the uncuffed endotracheal tube group (4.4%) difference was statistically significant (P = 0.027). No statistically significant incidence of laryngospasm, aspiration in Ryle's tube, and stridor was observed in any of the children. Even though I-Gel confers to the shape of the pharynx, larynx, and perilaryngeal structures it might have caused minor trauma to the mucosa leading to blood staining of the device. Hughes C et al [13] in 2012 and Hong JI et al. [8] in 2018, did similar studies and they did not observe a significant incidence of blood on the device, laryngospasm, and stridor between the two groups.

The incidence of cough post-extubation and after 6 hours in the uncuffed endotracheal tube group were 17.8% and 15.6% and in the I-Gel group were 2.2% and 0% respectively.

The incidence of sore throat in the uncuffed endotracheal tube group after extubation is 20% and after 6 hours is 17.8% as compared to 2.2% after extubation and 0% after 6 hours in the I-Gel group. Both cough and sore throat were found to be significantly higher in ETT group. Kohli M et al [6] in their study also observed statistical significant incidence of cough immediately postoperatively in the endotracheal tube group which was similar and comparable to the findings observed in our study. This could be because the endotracheal tube is more invasive and crosses the vocal cords which can incidentally lead to trauma of the vocal cords and lead to cough and sore throat.

Conclusion

Thus, we conclude from our study, that I-Gel is equally effective as the uncuffed endotracheal tube in providing adequacy of ventilation in paediatric patients. There were no hemodynamic changes in either of the groups.

The I-Gel group had a statistically significant blood staining as compared to the uncuffed endotracheal tube group. Whereas the uncuffed endotracheal tube group had a higher incidence of cough and sore throat after extubation and after 6 hours of removal of the device.

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