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A comparative study of I-GEL and endotracheal tube in children undergoing daycare surgeries- a prospective, randomized control study.

Dr.Ch. Sindhura[1], Dr.B.Sowbhagyalakshmi[2]
1 st Author: Ch. Sindhura-Postgraduate in Anaesthesia(M.D) ,Rangaraya Medical College, Kakinada
Corresponding Author: Dr.B.Sowbhagyalakshmi, HOD & Professor,Department of Anaesthesia RangarayaMedical College,Kakinada.

Abstract:
Introduction*: The I-GEL is a novel supraglottic airway device, made up of medical-grade thermoplastic elastomer. It's soft, non-inflatable cuff causes easier insertion, minimal tissue compression and stability after insertion. This study evaluated the effectiveness of I-GEL over endotracheal tube with regards to respiratory and hemodynamic parameters.*
Objective: *The study aimed to evaluate the safety of the I-GEL as an effective airway compared to the traditional endotracheal tube in paediatric patients undergoing day care surgeries.*
Methods: *After taking Institutional ethical committee approval, 60 children of age between 1 to 12 years, belonging to ASA PS class 1, undergoing elective daycare procedures such as herniotomy, orchidopexy, hypospadias repair, circumcision, rectal polyp removal over six months were included. They were randomly divided using a computer randomization software into I-GEL and ET Tube groups. Primary parameters measured were the number of attempts, insertion time, ease of insertion. Secondary parameters are hemodynamic variables.*
Results*: I-GEL was significantly better compared with ET tube in terms of the number of attempts, ease of insertion and insertion time. Increase in heart rate and Mean Arterial Pressure was higher following insertion of ET Tube in the first few minutes and subsequently became comparable.* ***Conclusion:*** *I-GEL is an easy, safe and effective alternative airway device compared to ET tube in children undergoing day care surgeries.*
Keywords*: I-gel,Endotrachealtube,airway, supraglottic airway device.*

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I. Background

The I-GEL is a second-generation supraglottic airway device, made up of medical-grade thermoplastic elastomer. It's soft, and noninflatable cuff causes easier insertion, minimal tissue compression and stability after introduction[1]. The insertion of i-gel is considered to be easier than other Supraglottic Airway Devices, and i-gel has the capacity to seal higher oropharyngeal leak pressures, compared with first-generation Supraglottic Airway Devices. This study is designed to evaluate the effectiveness of I-GEL over Endotracheal tube with regards to respiratory and hemodynamic parameters.

OBJECTIVE*:The study aimed to evaluate the safety of the I-GEL as an effective airway compared to the traditional endotracheal tube in pediatric patients undergoing day care surgeries*

INTRODUCTION: The I-gel is latex-free, gel-like, transparent and provides a noninflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures. I-Gel size 1.5 and above come with an integral gastric channel for suction of gastric contents. The primary aim was to determine ease of insertion of the i-gel airway and assess the adequacy of ventilation.

II. Materials and Methods

After taking Institutional ethical committee approval, 60 children of age between 1 to 12 years, belonging to ASA PS class 1, undergoing elective daycare procedures such as herniotomy, orchidopexy, hypospadias repair, circumcision, rectal polyp removal over six months were included in the study. Children with an Anticipated difficult airway, Oropharyngeal pathology, Inadequate fasting are excluded from the study. They were randomly divided using a computer randomization software into I-GEL and ET Tube groups. Primary parameters measured were the number of attempts, insertion time, ease of insertion. Secondary parameters are hemodynamic variables. All the surgeries are conducted under general anaesthesia. Patients

fasted for 6 hours prior to induction. All the children are given premedication with Inj. MIDAZOLAM 0.1-0.2mg/kg IM 30 minutes before induction. The pulse oximeter, Electrocardiography and Non-invasive blood pressure monitors are attached to the patients in the operating room. INDUCTION is done with Inj. FENTANYL 1-2 mcg/kg IV and Inj. PROPOFOL 2-2.5 mg/kg IV. Inj. ATRACURIUM 0.5mg/kg may or may not be given depending upon the surgical need and difficulty in establishing an airway. Manual Bag and Mask ventilation is done for 3 minutes, with 100 per cent oxygen before attempting to establish an airway. In the ET tube group, uncuffed tubes are used until five years of age, and cuffed tubes are used above five years. The appropriate size of Endo Tracheal tube is selected using modified Cole's formula. The ET tube was exchanged with the next smaller size(0.5mm) when resistance to intubation was faced. The cuff was inflated with minimal cuff volume required to seal. In the I-gel group, the appropriate size was selected according to the manufacturer's instructions and depending on the bodyweight of the child. I-gel of appropriate size was taken and lubricated with a water-based lubricant. After Preoxygenation, it is inserted into the oral cavity, moving the tongue anteriorly and out of its way, directed posteriorly against the hard palate and advanced with gentle pressure until the resistance was felt. Manipulations such as jaw thrust or slight twisting of the device were performed when needed. Correct placement of ET tube or I-Gel is identified by visible chest expansion, absence of audible leak during ventilation and square-shaped capnograph.Failure of establishing airway with I-Gel is defined as the failure to achieve adequate ventilation within two attempts. Anaesthesia is maintained with oxygen and nitrous oxide at 50:50 ratio and SEVOFLURANE 0.6 to 1 per cent as needed, with spontaneous or assisted ventilation. Tidal volume is kept at 6-8ml/kg to maintain ETCO2 between 30-40mm Hg. The primary parameters measured are Insertion time, Number of Insertion attempts and ease of insertion. Insertion time of the device was defined as the time from removal of the facemask to first capnograph trace. The number of insertion attempts are 1 or 2, after an unsuccessful second attempt, an alternate airway was used.

Ease of insertion is graded as:VERY EASY: when no manipulation is needed to establish the airway; EASY: when jaw thurst or external manipulation are needed to establish the airway; DIFFICULT: when device rotation and adjustment are needed. At the end of the surgery, nitrous oxide and sevoflurane were stopped, and paralysis was reversed using neostigmine and glycopyrrolate in cases that received atracurium.

III. Results

Statistical analysis:

1. $P< 0.05$ was considered statistically significant
2. Qualitative data were analyzed using the Chi-square test(sex, number of insertion attempts, ease of insertion)
3. Quantitative data between groups (age, weight, hemodynamic parameters after insertion of device, insertion time) was analyzed using Student's *t*-test.

Sample size calculation: For calculation of sample size, we have taken the primary outcome of our study, ease of insertion as a measure from a pilot study of 20 cases in each group. The incidence of very easy grade in I-gel group is 80%, and in ET tube group, it is 45%. Alpha error is taken as 0.05 and beta error as 0.2 and power is set at 0.8. Each group required a minimum sample of 29 cases, and we have taken 30 cases.

Comparing Patients' demographics between the I-Gel group and the ET tube group did not show any significance. The mean age in I-gel group is 6.98 years with a standard deviation of 1.34 whereas in the ET tube group the mean age is 7.24 years with a standard deviation of 2.13 and the p-value is 0.573 which is not significant. There are 24 male children and 6 female children in I-Gel group whereas 22 male children and 8 female children in the ET tube group. The p-value for sex distribution is 0.526, which is not significant. The mean weight of children in I-Gel group is 18.52 kgs, and in the ET tube group, it is 19.01 kgs which is again not significant, thus ruling out the bias caused by demographic variables.

We were able to establish the airway successfully in both I-Gel and ET tube groups in the first attempt itself. So, the number of insertion attempts is not significant between the groups.

The Insertion time in I-Gel group is 9.153 seconds with a standard deviation of 1.839, and in the ET tube group, it is 18.33 seconds with a standard deviation of 2.161. When these are compared using an independent T-test, the p-value comes to <0.001, which is statistically highly significant.

The ease of insertion of device in the I-gel group is graded as very easy in 26 cases, easy in 4 cases and difficult in 0 cases whereas in the ET tube group it is graded as very easy in 16 cases, easy in 12 cases and difficult in 2 cases. The p-value, in this case, is 0.0059, which is statistically significant.

The baseline means of heart rate and mean arterial pressure in I-Gel group and ET tube group are not significant. However, within the first 2 minutes of insertion of the airway device, heart rate and mean arterial pressure in the Et tube group is significantly higher than in the I-Gel group. Heart rate and Mean arterial pressure became non-significant by 5 minutes after insertion of the airway device.

In our observation for perioperative complications, no patient of either group developed severe airway leakage or airway obstruction or desaturation or laryngospasm or aspiration during the course of surgical procedure. 3 out of 30 patients in the ET tube group were found to have blood on the Et tube after extubation, but it did not happen with any of the cases from I-Gel group. One patient from I-Gel group and six patients from the ET tube group had a postoperative cough. Six patients from the ET tube group complained of sore throat postoperatively within 24 hours of completion of the surgery, but none from the I-Gel group complained of Sore throat. Nevertheless, these cannot be statistically analyzed as the study group are children from 1 to 12 years, and most of them cannot complain of any sore throat reliably.

IV. Discussion

The invention of Supraglottic airway devices has revolutionized the perspective of airway management during anaesthesia and emergency. These devices need to be studied in our patient groups before taking up into standard care. Our study aims to compare the Second generation supraglottic airway device I-Gel with Standard Airway management device, the endotracheal tube.

The shape, softness and contours of I-Gel accurately mirror the perilaryngeal anatomy creating the perfect fit of the airway[1]. So, cuff inflation is not required. Also, this perfect fit causes the Trauma caused by compression of tissues and hazards of displacement of the device to be significantly reduced. The noninflatable cuff is semirigid and cannot be folded over, overinflated, or inserted in the trachea, thus diminishing the risk of airway obstruction.

No significant differences were found among the age, sex and weight distributions of I-Gel and ET tube groups. Insertion of the device is obtained in the first attempt itself in all the cases. I-GEL was significantly better compared with the ET tube in terms of insertion time($p<0.001$). The mean insertion time is 9.153 seconds. The grading of ease of insertion was significant in I-Gel group compared to the ET tube group. Increase in heart rate and Mean Arterial Pressure was higher following insertion of ET Tube in the first few minutes and subsequently became comparable. I-Gel provided better hemodynamic stability compared to laryngoscopy and intubation.

The greater alveolar ventilation to functional residual capacity(FRC) ratio in the child(5:1) compared with the adult(1.5:1) increases the risk of haemoglobin desaturation during airway establishment. Lower age was associated with a shorter time required for desaturation during apnoea. Achievement of effective preoxygenation in the young child is often more difficult than in an adult. Thus, the difference in insertion time between I-gel and ET tube is considered clinically meaningful in children. Blood pressure and heart rate were higher in ET tube group, compared with the I-gel group, following intubation. Oropharyngeal and laryngotracheal stimulation after laryngoscopy and tracheal intubation provoke sympathoadrenal discharge, leading to hemodynamic changes.

Tandale and others did a study on Evaluation of the I-gel in children undergoing day care surgery in which they compared 1.5,2 and 2.5 size I-gels among 120 children and found that first attempt was successful in 94.11% cases and the mean insertion time to be 9.5 seconds[2].Theiler and others compared Performance of the pediatric sized I-gel with the AmbuAuraOnce laryngeal mask in anaesthetized and ventilated children and found the first attempt success rate with I-gel to be 91% and the insertion time to be 27+-11seconds[3].Richez and others did an observational study of the I-gel in 71 women and found that insertion was easy and performed in the first attempt in each patient, and only one case of cough and sore throat occurred[4]. Beylacq and others did an observational study of the I-gel in 50 children and found that all devices were inserted in the first attempt[5]. Saran and others compared I-gel and LMA-ProSeal in pediatric patients under controlled ventilation and found the mean insertion time in I-gel group to be 17.2 seconds, and achieved satisfactory airway in the first attempt in 26 cases among 30 cases and required manipulation in 2 cases without any perioperative complications[6]Maitra and others did a meta-analysis of the evaluation of i-gel airway in children and found that i-gel provided a significantly higher oropharyngeal leak pressure than LMA Proseal[7]. Goyal and others compared to size 2 I-gel with LMA-ProSeal and LMA-Classic in spontaneously breathing children undergoing elective surgery and found I-gel insertion to be easy and the first attempt success rate to be 95%. There was no change in blood pressure, heart rate, oxygen saturation on insertion. There were no clinically important complications in the postoperative period with I-gel[8]. Francksen and others compared I-gel with LMA- Unique in non-paralysed anaesthetized adult patients and found time and ease of insertion to be comparable, but the significantly higher airway leak pressure of I-gel is advantageous[9] Kohli and others compared I-gel and Endotracheal tube for the adequacy of ventilation in pediatric patients undergoing laparoscopic surgeries[10]. They found that 77.5% of I-gel cases were successful in the first attempt whereas 97.5% of ET tube cases were successful in the first attempt and Hemodynamics were stable for the I-Gel group compared to the Endotracheal tube group.

V. Conclusion

I-GEL is an easy, safe and effective alternative airway device compared to ET tube in children undergoing day care surgeries. Its faster insertion exposes the child to a very short apnoea time and has stable Hemodynamics following its insertion with an advantage of reduced postoperative sore throat and cough.

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I-GEL SIZE	*MANUFACTURER'S RECOMMENDED WEIGHT RANGE(KG)*	*NUMBER OF SUBJECTS IN THE STUDY*
1.5	*5-12*	*11*
2	*10-25*	*16*
2.5	*25-35*	*3*

Table 1I-GEL AND ET TUBE SIZES

SAMPLE SIZE:

Dichotomous Endpoint, Two Independent Sample Study

Sample Size	
Group 1	29
Group 2	29
Total	**58**

Study Parameters	
Incidence, group 1	80%
Incidence, group 2	45%
Alpha	0.05
Beta	0.2
Power	0.8

$$N_1 = \left\{ z_{1-\alpha/2} * \sqrt{\bar{p} * \bar{q} * (1 + \frac{1}{k})} + z_{1-\beta} * \sqrt{p_1 * q_1 + (\frac{p_2 * q_2}{k})} \right\}^2 / \Delta^2$$

$$q_1 = 1 - p_1$$

$$q_2 = 1 - p_2$$

$$\bar{p} = \frac{p_1 + kp_2}{1 + K}$$

$$\bar{q} = 1 - \bar{p}$$

$$N_1 = \left\{ 1.96 * \sqrt{0.62 * 0.38 * (1 + \frac{1}{1})} + 0.84 * \sqrt{0.8 * 0.2 + (\frac{0.45 * 0.55}{1})} \right\}^2 / 0.35^2$$

$$N_1 = 29$$

$$N_2 = K * N_1 = 29$$

p_1, p_2 = proportion (incidence) of groups #1 and #2
$\Delta = |p_2 - p_1|$ = absolute difference between two proportions
n_1 = sample size for group #1
n_2 = sample size for group #2
α = probability of type I error (usually 0.05)
β = probability of type II error (usually 0.2)
z = critical Z value for a given α or β
K = ratio of sample size for group #2 to group #1

Table 2DEMOGRAPHIC VARIABLES

PATIENT CHARACTERS	I-GEL(N=30)	ET TUBE(N=30)	P VALUE
AGE(YEARS)	6.98(SD 1.34)	7.24(SD 2.13)	0.573
SEX(M/F)	24/6	22/8	0.526
WEIGHT(KG)	18.52	19.01	0.478

Table 3 PRIMARY OUTCOMES

OUTCOME	I-GEL GROUP	ET TUBE GROUP	P-VALUE
SIZE 1.5/2.0/2.5	11/16/3		
4/4.5/5.0/5.5/6.0		3/5/9/10/3	
INSERTION ATTEMPTS(1/2)	30/0	30/0	1.000
INSERTION TIME (SECONDS)	9.153	18.33	<0.001
EASE OF INSERTION (VE/E/D)	26/4/0	16/12/2	0.0059

Table 4INSERTION TIME

GROUP	MEAN	STANDARD DEVIATION	SAMPLE SIZE
I-GEL	9.153	1.839	30
ET TUBE	18.33	2.161	30

- Analysed by independent T test
- Pooled standard deviation: 2.006

- t = -17.714
- Df = 58.0P = <0.001

Table 5 CHANGES IN HEART RATE

HEART RATE	I-GEL	ET TUBE
BASE LINE	90.6	92.6
1 MIN	92.4	102.5
2 MIN	90.8	100.4
3 MIN	88.6	95.8
5 MIN	88.4	93.4

Table 6CHANGES IN MEAN ARTERIAL PRESSURE

MEAN ARTERIAL PRESSURE	I-GEL	ET TUBE
BASE LINE	68.0	69.2
1 MIN	70.1	75.5
2 MIN	71.2	74.8
5 MIN	70.4	71.6
10 MIN	68.4	70.6

Table 7PERIOPERATIVE COMPLICATIONS

COMPLICATION	I-GEL	ET TUBE
SEVERE AIRWAY LEAKAGE	0	0
AIRWAY OBSTRUCTION	0	0
DESATURATION	0	0
BLOOD ON DEVICE	0	3
COUGH	1	6
SORE THROAT	0	6
LARYNGOSPASM/ STRIDOR	0	0
REGURGITATION/ ASPIRATION	0	0

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