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Original Article

Anesthetic Experience with I-Gel in Pediatric Patients by Residents in a Tertiary Care Hospital: An Observational Study

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Abstract

Introduction: The objective of this study was to demonstrate and determine the depth of insertion of I-gel in pediatric patients undergoing short surgical procedures and to tabulate the experience of using I-gel by the residents.

Methods: As there was no horizontal line in the pediatric I-gel sizes 1, 1.5, 2, and 2.5 (representing the correct position of the level of tooth after insertion), so the ideal depth of I-gel insertion could not be elucidated. Hence, this study was conducted. In this randomized prospective single hospital study 200 children, aged 1-12 years, the American Society of Anesthesiologists score I-II, weighing 5-35 kg undergoing minor surgical procedures, were observed. I-gel sizes used were 1.5, 2, and 2.5, respectively, as per body weight. The following characteristics were evaluated: I-gel placement time, the distance from the connector wing to the teeth level of patient post placement, success rate of the I-gel airway and gastric tube placement, oropharyngeal leak pressure and any associated complications. Statistical data was analyzed using appropriate statistical tests and any $P < 0.05$ was considered statistically significant.

Results: I-gel placement was 100% successful for sizes 2 and 2.5 and 95.4% for I-gel size 1.5. The overall I-gel placement success rate and the success rate at first attempt were 99% and 95%. The insertion distance from the connector wing to the teeth was estimated to be 4.4-6 cm for 1.5 size, 5.2-6.4 cm for 2 size, 4.5-6.9 cm for 2.5 size I-gel, respectively.

Conclusion: These results show that the I-gel is a safe and effective airway device for use by residents who probably do not have enough experience with the use of I-gel.

Key words: I-gel, Pediatric airway, Supraglottic airway device

INTRODUCTION

The I-gel™ (Intersurgical, UK) is a second generation single use, supraglottic airway device, made up of thermoplastic elastomer. The device is transparent and latex free and has a gel like cuff made of styrene ethylene butadiene styrene which provides a noninflatable anatomical seal of the pharyngeal and perilaryngeal structures.[1] Compared to the adult variants, the pediatric variants of I-gel size 1, 1.5, 2, and 2.5 lack a depth insertion marker. Hence, identification of proper placement of these pediatric variants of I-gel is difficult. The safety and efficacy of I-gel in Indian pediatric and adult population has been proved by anesthesiologist experienced in placing supraglottic airway devices,[2,3] but the safety and efficacy of the I-gel at the hands of inexperienced anesthesia residents has not been evaluated neither has been the adequate depth of I-gel placement ever evaluated in the Indian pediatric population. Hence, we designed an observational study to document the experience of residents while using the I-gel sizes 1.5, 2, and 2.5 in pediatric patients. Our aim was to determine the success rate, ease of insertion, insertion time, and insertion depth of I-gel. Furthermore observed were the oropharyngeal leak pressure, ease of placement of

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gastric drain tube through I-gel and complications during insertion if any.

MATERIALS AND METHODS

After approval from the institutional ethics committee and departmental permission, this prospective observational study was conducted jointly under the Department of Anaesthesiology and Critical Care and the Department of Paediatric Surgery, Gauhati Medical College, Guwahati Assam, India. For our study, 200 children were observed over a period of 4 months. Informed consent was obtained from the parents before the start of this study. Children of the American Society of Anesthesiologists (ASA) I or II, aged between 1 and 12 years, weighing between 5 and 35 kg undergoing elective procedures in supine position of <90 min duration such as hypospadias repair, colostomy closure, herniotomy, orchiopexy, circumcision, rectal polyp etc. Removal were included in our study population. Exclusion criteria included patients having anticipated difficult airway, oropharyngeal pathology, at risk of aspiration and patients undergoing thoracic, neurosurgical, spine or otolaryngological procedures. They were divided into three groups based on body weight, Group 1: 5-12 kg ($N = 42$), Group 2: 12-25 kg ($N = 98$), and Group 3: 25-35 kg ($N = 60$). All patients were premedicated with nasal midazolam 0.3 mg/kg 20 min before the start of the operative procedure. Standard perioperative monitoring was performed as per ASA guidelines. Patients were administered injection fentanyl 2 mcg/kg intravenous (IV) before induction. Inhalational induction with sevoflurane in oxygen or IV with propofol 2 mg/kg was done. Muscle relaxant injection atracurium 0.5 mg/kg was used at the time of induction followed by divided doses if required intraoperatively. When the patient was in an adequate plane of anesthesia a lubricated I-gel of appropriate size was inserted into the oral cavity, directed posteriorly against the hard palate and advanced with gentle pressure until the resistance was felt. To aid I-gel placement jaw thrust or slight twisting of device in the oropharynx were performed. Correct placement of I-gel was assessed by a visible chest expansion, the absence of audible leak and a square-shaped capnogram observed during ventilation. After proper fixation of the I-gel, lubricated gastric tube of appropriate size was placed through the gastric channel in all the patients. Anesthesia was maintained with O_2 and N_2O in (1:1) ratio with sevoflurane 2% using a circle absorber with controlled ventilation. All patients were ventilated with a tidal volume of 6-8 ml/kg to maintain an end-tidal carbon dioxide between 30 and 40 mmHg. The following parameters were noted ease and success rate of I-gel insertion, number of insertion attempts, insertion distance (ID), I-gel insertion time (IT), oropharyngeal leak pressure, ease of I-gel, and gastric tube insertion, any complications associated.

Insertion Time (IT) of I-gel

Time between pick up of device and establishment of adequate ventilation.

Insertion Distance (ID) of I-gel

Distance from the connector wing of I-gel to the teeth position marked after fixing the I-gel.

Oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and observing the airway pressure at which an audible leak and/or an audible noise with stethoscope placed just lateral to thyroid cartilage was heard.

Failure of I-gel airway placement was defined as failing to achieve adequate ventilation with two attempts of I-gel insertion. In the case of failure to achieve adequate ventilation with two attempts of I-gel, endotracheal intubation was done, and it was considered as a failure of I-gel airway. At the end of surgery, stomach was aspirated with the help of the gastric tube and neuromuscular blockade was adequately reversed in patients. Clinical judgment was used to determine the best time for removal of the I-gel after appearance of airway reflexes. All the I-gel placement in our study, patients were done under the supervision of experienced anesthesiologist by anesthesia residents having very less experience with the use of I-gel in pediatric patients.

Ease of I-gel placement was evaluated as per Tandale *et al.*[4] and further graded as:

- Very easy: No resistance to insertion in the pharynx in a single maneuver
- Easy: When insertion into the pharynx required maneuver like jaw thrust
- Difficult: When more than two manoeuvres were needed such as device rotation and jaw thrust.

The ease of placement of gastric drainage tube through I-gel was recorded as per Tandale *et al.*[4] and further graded as:

- Easy: Passage of gastric drainage tube without resistance and confirmed by auscultation over epigastrium
- Difficult: Resistance to placement of gastric drainage tube requiring manipulation of I-gel.

Statistical Analysis

The statistical analyses was done using "GraphPad InStat-version 21.0" software. Data obtained as per predesigned proforma (Annexure 1) was entered into Microsoft Excel spreadsheet and assessed using appropriate statistical methods using two-tailed *t*-test, Chi-square test and Mann–Whitney test wherever applicable. Data was expressed as mean and standard deviation, proportion. As no previous data regarding insertion depth of I-gel was available in the

Indian pediatric population, our study was a pilot study conducted to obtain data on the depth of insertion needed for pediatric I-gel, based on which future trials could be conducted.

RESULTS

Demographic parameters and mean surgical time of our study patients are represented in Table 1.

The ID of I-gel in Groups 1, 2, and 3 varied as 4.4-6, 5.2-6.4, and 4.5-6.9 cm, respectively (Figure 1). The mean ID of I-gel was greatest in Group 2 patients and the lowest in Group 1 patients.

The overall I-gel placement success rate was highest in Groups 2 and 3 patients with the highest first attempt success rate observed in Group 3 patients (Table 2). Successful placement of I-gel at first attempt was possible in overall 95% of the patients (Table 3).

The mean insertion time of I-gel was highest in Group 2 and lowest in Group 1 patients, the insertion time observed in Groups 1, 2, and 3 patients varied as 15-19, 15-23, and 16-20 s, respectively (Figure 2).

I-gel placement was very easy in 92%, easy in 6%, and difficult in 1% of the patients (Table 2). Highest ease of insertion of I-gel was noted in Group 2 patients, insertion was most difficult in Group 1 patients. In 2 patients of Group 1 (1%), I-gel could not be inserted (Table 2).

Nasogastric tube placement through I-gel was successful in our study patient. Gastric tube placement through I-gel was easiest among Group 3 patients and most difficult among Group 1 patients (Table 4).

The mean airway leak pressure was highest in Group 2 and lowest in Group 3 patients (Figure 3).

Higher incidence of complication was observed in Group 1 patients compared to Group 2 and 3, I-gel displacement being the most common complication observed in our study patients (Table 5).

DISCUSSION

The study was conducted to evaluate the safety and efficacy of the I-gel supraglottic airway device in children across a wide spectrum of age and various I-gel sizes. We successfully evaluated the various sizes of I-gel in pediatric patients in a large study population. Our study results showed that I-gel had provided an effective airway in 198 (99%) children. The ID for 1.5, 2, and 2.5 size I-gel was observed to be 4.4-6, 5.2-6.4, and 4.5-6.9 cm, (95% confidence interval) respectively, which was similar to study

Table 1: Patient demographic and clinical profile

Demographic variables	Group 1 *N*=42	Group 2 *N*=98	Group 3 *N*=60
Age (months)	14±5	60±8	108±10
Gender (M/F)	30/12	64/34	38/20
Weight (kg) (M/F)	5±2/6±1	12±3/14±5	23±6/28±7
Inhalation/IV induction	32/10	74/24	42/18
% percentage	(76/24)	(75/25)	(70/30)
Surgical time (min)	56±16	68±14	58±24

IV: Intravenous

Table 2: Ease of placement score for I-gel

Parameters	Group 1 *N*=40 (%)	Group 2 *N*=98 (%)	Group 3 *N*=60 (%)	Overall success (%)
Very easy (1)	35 (83.3)	93 (94.9)	56 (93.33)	92
Easy (2)	3 (7)	5 (5.1)	4 (6.67)	6
Difficult (3)	2 (4.7)	0	0	1

Table 3: Success rate of I-gel

Parameters	Group 1 *N*=42 (%)	Group 2 *N*=98 (%)	Group 3 *N*=60 (%)	Overall success %
Insertion attempts 1	38 (90.4)	93 (94.89)	59 (95)	95
Insertion attempts 2	2 (4.7)	5 (5.11)	1 (5)	4
Overall	95.1	100	100	99

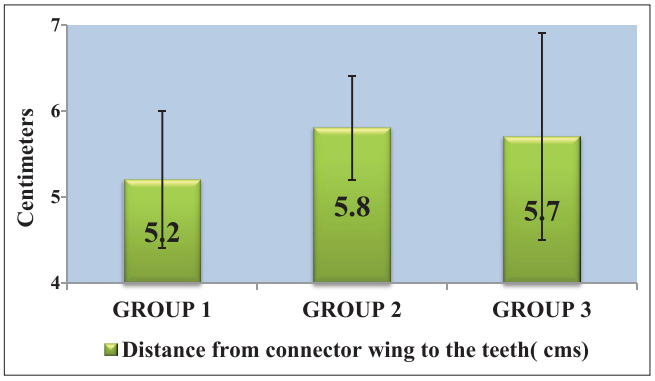

Figure 1: Insertion distance of I-gel

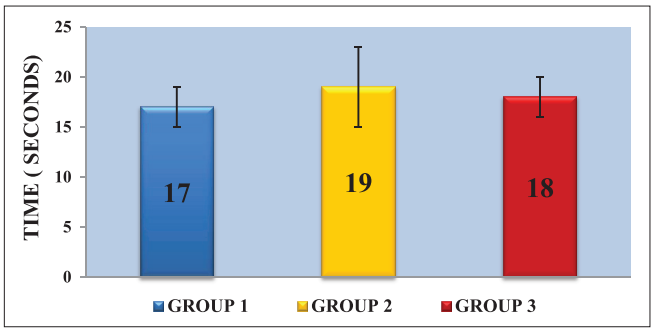

Figure 2: I-gel insertion time

Table 4: Ease of insertion score for gastric tube

Parameters	Group 1 *N*=40 (%)	Group 2 *N*=98 (%)	Group 3 *N*=60 (%)
Easy (1)	38 (95)	97 (98.98)	60 (100)
Difficult (2)	2 (5)	1 (1.02)	0
Overall	100	100	100

Table 5: Overall complications of I-gel placement

Complications	Group 1 *N*=42 (%)	Group 2 *N*=98 (%)	Group 3 *N*=60 (%)
Trace bleeding	1 (2.3)	0	0
Displacement	3 (7.1)	1 (1)	1 (1.67)
Hypoxemia	1 (2.3)	0	0

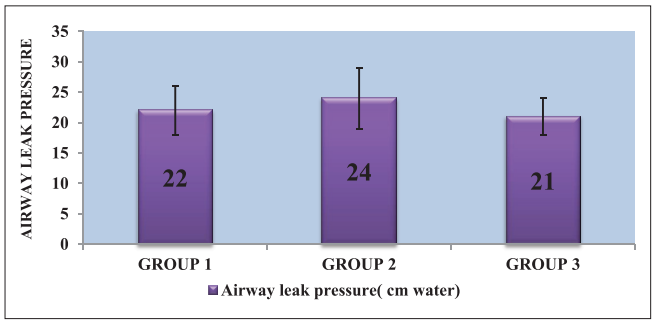

Figure 3: Airway leak pressure of I-gel

done by Abukawa *et al.*[5] to evaluated the safety and efficacy of I-gel in African pediatric population. Two patients in our study had failure of I-gel placement, requiring endotracheal intubation. I-gel placement was 100% successful for I-gel sizes 2 and 2.5 and 95.4% for I-gel size 1.5. The overall I-gel placement success rate and the success rate at first attempt were 99% and 95%, similar to the results obtained by Abukawa *et al.*[5] Beringer *et al.*[6] who had prospectively observed the use of I-gel sizes 1.5, 2, and 2.5, had also obtained similar I-gel placement success rate, in spite of the fact that there experienced anesthesiologist had performed I-gel placement compared to inexperienced residents in our study. Overall I-gel insertion time observed in our study ranged from 15 to 20 s. I-gel insertion time of 11-19 s in adult and pediatric patients has been reported as per available literature.[7,8] Abukawa *et al.*[5] had reported a higher mean I-gel insertion time of 24 s which was probably due to operator inexperience. The oropharyngeal leak pressure observed in other studies varied between 18 and 28 cm of water[5-9] Gastric tube placement through I-gel was difficult in 1.5% of the patients for sizes 1.5 and 2 compared to Tandale *et al.*[4] where <1% of patients had difficult gastric tube placement through 1.5 size. Saran *et al.*[10] had compared the use of I-gel and ProSeal laryngeal mask airway among pediatric patients and had obtained similar success rate for I-gel. The fact that in the study by Saran *et al.*,[10] I-gel placement was done by an anesthesiologist experienced in placing supraglottic airways compared to inexperienced residents in our study; further validates our study results. Complications such as displacement, hypoxia, and trace bleeding were observed in few of our study patients and were mostly observed with the size 1.5 of I-gel. Higher incidence of I-gel placement failure, difficulty in gastric tube insertion, and complications were mostly observed with the 1.5 size of I-gel.

Limitations of our study include nonconfirmation of proper I-gel placement using a fiberscope. Our study did not estimate the ID of I-gel in infants. Neither randomisation nor blinding could be done in our study patients. Multicentric prospective studies are needed to reconfirm our study results.

CONCLUSION

Our study showed that I-gel airway is a safe and effective device for use by the resident anesthesiologist for perioperative pediatric airway management.

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ANNEXURE 1

Proforma

Name:
Age: Sex:
Hospital No.: MRD No.:
Address:

Phone No.:
Weight: Height:

History

Patient having any history of the following:

- With difficult airway or anticipated difficult airway (Yes/No)
- Oropharyngeal pathology (Yes/No)
- Risk of aspiration (Yes/No)
- Undergoing thoracic, neurosurgical, spine, and ENT procedures (Yes/No)

Examination

ASA status: MET:
Pulse: Blood pressure:
Chest: CVS:
CNS:

I-gel Assessment

Correct placement of I-gel assessment:

- Symmetrically visible chest expansion (Yes/No)
- A square-shaped capnograph (Yes/No)
- Absence of audible leak during ventilation (Yes/No).

I-gel insertion time (s):

I-gel insertion distance (cm):

Number of insertion attempts:

Ease of insertion of I-gel (Very easy/Easy/Difficult):

Ease of gastric drainage tube through I-gel (Easy/Difficult)

Any maneuver done during I-gel insertion:

Insertion time of I-gel: Time between pick up of device and establishment of adequate ventilation.

Insertion distance (ID): Distance from the connector wing of I-gel to the teeth position marked after fixing the I-gel.

Failure of I-gel airway: Failure to achieve adequate ventilation with two attempts of I-gel insertion.

Oropharyngeal leak pressure: Oropharyngeal leak pressure will be determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and the airway pressure at which an audible leak and/or an audible noise with stethoscope placed just lateral to thyroid cartilage was heard was noted.

Ease of I-gel insertion was recorded as:

- Very easy: No resistance to insertion of I-gel in the pharynx in a single maneuver
- Easy: When insertion of I-gel into the pharynx required maneuver like jaw thrust
- Difficult: When more than two maneuvers were needed such as device rotation and jaw thrust during I-gel insertion.

The ease of placement of gastric drainage tube was recorded as:

- Easy: Passage of gastric drainage tube without resistance and confirmed by auscultation over epigastrium.
- Difficult: Resistance to placement of gastric drainage tube requiring manipulation of I-gel.