Scholars Academic Journal of Biosciences (SAJB) **ISSN 2321-6883 (Online)**
Sch. Acad. J. Biosci., 2017; 5(6):453-458 **ISSN 2347-9515 (Print)**

(An International Publisher for Academic and Scientific Resources)
www.saspublishers.com DOI : 10.36347/sajb.2017.v05i06.008

Original Research Article

Evaluation of I-Gel in Paediatric Patients

Ankur Garg[1], Jyotsna Agarwal[2], Anita Malik[2], Shobhna Jafa[2], Rajni Kapoor[2], Rita Wahal[2].
[1]resident, Department of Anaesthesiology, King George`s medical university, Lucknow, India.
[2]professor, Department of Anaesthesiology, King George`s medical university, Lucknow, India.

***Corresponding author**
Dr. Ankur Garg
Email: ankurgarg.gsvm@gmail.com

Abstract: Maintenance of airway is an integral part of general anaesthesia. Nowadays supraglottic airway devices are routinely used for short-term elective surgery. I-gel is one of the newer single-use, supraglottic airway for use in anaesthesia with the potential advantage of easy insertion and minimal risk of tissue compression with stability after insertion. The aim is to evaluate the ease of insertion of I-gel, insertion time, quality of ventilation, suitability of the size recommended in relation to patient`s weight, stability of the device, ease of Ryles tube insertion, haemodynamic stability and potential complications. After a complete preanaesthetic checkup of patients scheduled for elective surgery, the patient was taken in the operating room and was monitored by pulse oximetry, end tidal CO2, noninvasive arterial blood pressure and electrocardiogram. Patient was premedicated, preoxygenated and was induced with propofol. After induction I-gel was inserted and proper insertion was assessed by observing the end tidal carbon dioxide square waveform and chest movements. Gastric insufflation was assessed by auscultation over the patient's epigastric area. Anaesthesia was then maintained on O2 + N2O + Isoflurane. All the patients remained on spontaneous ventilation throughout the surgery. We found that the insertion of the I-gel was easy in 88% cases and in 90% cases it was successful on 1st attempt, mean duration of insertion was 8.02 ± 2.45 sec, size was found to be 'suitable" (76.0%), Ryle's tube insertion was "easy" in 100% patients and insertion time was 4.34 ± 0.48 sec. Haemodynamically patients were found to be stable throughout the surgery. In our study we have found that insertion was easy, haemodynamically the patient was stable throughout the surgery, quality of ventilation and oxygenation was also found to be good and there were very few post-operative complications.
Keywords: I-gel, anesthesia, airway, child, isoflurane.

INTRODUCTION:

Maintenance of airway is an integral part of general anaesthesia. Nowadays supraglottic airway devices are routinely used for short-term elective surgery, and have been shown to be safe and effective in spontaneously breathing patients and in patients undergoing pressure-controlled ventilation, with lesser number of side effects as compared to endotracheal intubation [1]. I-gel is a new single-use, non-inflatable supraglottic airway for use in anaesthesia during spontaneous or intermittent positive pressure ventilation. It is a truly anatomical airway device; its design was inspired by the physiology of the perilaryngeal framework itself. I-gel has several potential advantages including easier insertion, minimal risk of tissue compression with stability after insertion and an integrated gastric channel is provided for gastric suction or passage of nasogastric tube to empty the stomach [2]. Pediatric sized I-gel was launched in the latter half of 2009 so there were fewer evidences to prove effectiveness of this device in pediatric patients so the present study was undertaken to evaluate the safety and effectiveness of I-gel in pediatric patients for maintenance of anaesthesia [3].

AIM:

To evaluate the ease of insertion of I-gel, insertion time, quality of ventilation, suitability of the size recommended in relation to patient`s weight, stability of the device (In flexion, extension, lateral rotation of neck), ease of Ryles tube insertion (ease of insertion, time of insertion, aspirate), haemodynamic stability and potential complications.

MATERIALS AND METHOD:

Prospective observational study was conducted on 50 children weighing 5 -30kg, belonging to ASA grade 1-2 and scheduled for elective surgery under general anaesthesia. Patients with previous or anticipated airway problems, pathology of airway, respiratory tract, full stomach patients and surgery greater than 90 mins duration were excluded from the study. A thorough medical history was obtained and

complete preanaesthetic checkup of the patient was done and informed consent was obtained in all cases.

In the operating room each patient was routinely monitored by pulse oximetry, end tidal CO_2, noninvasive arterial blood pressure and electrocardiogram. Premedication with intravenous glycopyrrolate (0.005 mg/kg), midazolam (0.02mg/kg) and fentanyl (2mcg/kg) was done; Patients breathed 100% oxygen by facemask for a minimum of 3 min. Anesthesia was induced with propofol (2mg/kg). On loss of verbal contact/crying, I-gel was inserted in accordance with manufacturer's guidelines [4]. Adequate placement of the device was assessed by gently squeezing the reservoir bag and observing the end tidal CO_2 square waveform and chest movements. If ventilation was inadequate, the following manipulations were allowed: gentle pushing or pulling of the device, chin lift, jaw thrust, neck extension or flexion. The number of attempts required for insertion was recorded. If the device was not successfully inserted by the second attempt, this was taken as a failure of the I-gel. Gastric insufflations were assessed by auscultation over the patient's epigastric area. Anaesthesia was then maintained on O_2 + N_2O +/- Inhalational anaesthetic (Isoflurane). All the patients remained on spontaneous ventilation throughout the surgery. Following completion of the surgery the I-gel was removed and any visible blood on the device was noted.

Continuous data were summarized as mean ± SD while discrete (categorical) in number and percentage. Groups were compared by one way analysis of variance (ANOVA) and the significance of mean difference from baseline to other periods was compared by Dunnett's post hoc test. Analysis was performed on STATISTICA (windows version 6.0) software.

RESULTS:

A total of 50 pediatric patients of either sex were evaluated. The primary outcome measures of the study was heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation (SPO_2), end tidal CO_2 ($ETCO_2$)) changes during surgery and the secondary outcome measure was the complications after the removal of I-gel. The basic, clinical, primary and secondary outcome measures of the operated children are summarized below in section A to D, respectively.

Basic characteristics

All children ranged from 2-13 yrs with mean (± SD) 5.80 ± 3.39 yrs and median 5 yrs. Similarly, the weight of all children ranged from 8-28 kg with mean (± SD) 16.54 ± 6.05 kg and median 16 kg.

Clinical characteristics

At presentation, the ASA grade of all patients was "1" (100.0%). The duration of surgery ranged from 40-90 min, insertion time for I-gel ranged 5-16 sec and Ryle's tube insertion ranged 4-5 sec, with mean (± SD) 72.20 ± 12.82 min, 8.02 ± 2.45 sec and 4.34 ± 0.48 sec, respectively with median 70 min, 8 sec and 4 sec, respectively. In most of the patients, the insertion of I-gel was in 1 attempt (90.0%). The quality of ventilation was "excellent" (100.0%). The device was found to be stable in all (100%) patients. The Ryle's tube insertion (ease) was "easy" (100.0%).

Primary outcome measures- hemodynamic changes

I. Heart rate (HR) -The pre and post induction HR of pediatric patients during surgery are summarized in table 1. During the period, the mean HR ranged from 105.68 (30 and 40 min) to 114.52 beats/min (after induction). ANOVA revealed a significant effect of time (periods) on HR ($F=4.24$, $p<0.001$). Further, Dunnett's test revealed that the mean HR was significantly ($p<0.01$) different and higher after induction as compared to baseline. However, in rest of the periods it did not differ significantly ($p>0.05$) as compared to baseline i.e. found to be statistically similar.

Table 1: HR levels of pediatric patients during the surgery periods

Periods	N	Mean ± SD	Mean difference (from baseline)	q value	p value
Baseline	50	107.20 ± 9.27	Ref		
After induction	50	114.52 ± 10.30	7.32	4.52	p < 0.01
5 min	50	109.40 ± 7.07	2.20	1.36	p > 0.05
10 min	50	107.18 ± 6.30	0.02	0.01	p > 0.05
15 min	50	107.46 ± 5.73	0.26	0.16	p > 0.05
20 min	50	106.40 ± 9.08	0.80	0.49	p > 0.05
30 min	50	105.68 ± 9.17	1.52	0.94	p > 0.05
40 min	50	105.68 ± 7.33	1.52	0.94	p > 0.05
50 min	49	105.73 ± 7.84	1.47	0.90	p > 0.05
60 min	47	106.17 ± 7.35	1.03	0.63	p > 0.05
70 min	34	106.68 ± 7.81	0.52	0.29	p > 0.05
80 min	20	107.85 ± 8.79	0.65	0.30	p > 0.05
90 min	11	105.91 ± 8.96	1.29	0.48	p > 0.05

II. Systolic blood pressure (SBP) - The pre and post induction SBP of pediatric patients during surgery are summarized in table 2. During the period, the mean SBP ranged from 99.64 (15 min) to 106.58 mmHg (after induction). ANOVA revealed a significant effect of time on SBP ($F=7.81$, $p<0.001$). Further, Dunnett's test revealed that the mean SBP differed and lowered significantly ($p<0.05$ or $p<0.01$) from 5 min to 40 min as compared to baseline. However, in rest of the periods it did not differed ($p>0.05$) as compared to baseline i.e. found to be statistically the same.

Table 2: SBP levels of pediatric patients during the surgery periods

Periods	N	Mean ± SD	Mean difference (from baseline)	q value	p value
baseline	50	106.16 ± 6.44	Ref		
After induction	50	106.58 ± 6.74	0.42	0.38	p > 0.05
5 min	50	102.84 ± 5.93	3.32	2.98	p < 0.05
10 min	50	101.08 ± 5.67	5.08	4.56	p < 0.01
15 min	50	99.64 ± 5.40	6.52	5.86	p < 0.01
20 min	50	100.48 ± 4.13	5.68	5.10	p < 0.01
30 min	50	101.04 ± 4.11	5.12	4.60	p < 0.01
40 min	50	102.60 ± 5.17	3.56	3.20	p < 0.05
50 min	49	104.65 ± 6.03	1.51	1.35	p > 0.05
60 min	47	105.19 ± 4.88	0.97	0.86	p > 0.05
70 min	34	104.94 ± 6.39	1.22	0.98	p > 0.05
80 min	20	103.80 ± 5.94	2.36	1.60	p > 0.05
90 min	11	104.18 ± 4.24	1.98	1.07	p > 0.05

III. Diastolic blood pressure (DBP) - The pre and post induction DBP of pediatric patients during surgery are summarized in table 3. During the period, the mean DBP ranged from 55.56 (15 min) to 63.04 mmHg (after induction). ANOVA revealed a significant effect of time on DBP ($F=12.53$, $p<0.001$). Further, Dunnett's test revealed that the mean DBP differed and lowered significantly ($p<0.05$ or $p<0.01$) from 5 min to 80 min as compared to baseline. However, in rest of the periods (after induction and 90 min) it did not differed ($p>0.05$) as compared to baseline i.e. found to be statistically the same.

Table 3: DBP levels of pediatric patients during the surgery periods

Periods	N	Mean ± SD	Mean difference (from baseline)	q value	p value
baseline	50	61.80 ± 4.47	Ref		
After induction	50	63.04 ± 4.61	1.24	1.53	p > 0.05
5 min	50	59.16 ± 3.90	2.64	3.25	p < 0.05
10 min	50	57.04 ± 4.09	4.76	5.85	p < 0.01
15 min	50	55.56 ± 3.62	6.24	7.67	p < 0.01
20 min	50	56.08 ± 3.43	5.72	7.03	p < 0.01
30 min	50	58.04 ± 3.71	3.76	4.62	p < 0.01
40 min	50	58.04 ± 3.86	3.76	4.62	p < 0.01
50 min	49	58.29 ± 4.51	3.51	4.30	p < 0.01
60 min	47	59.02 ± 3.77	2.78	3.36	p < 0.01
70 min	34	59.18 ± 3.94	2.62	2.90	p < 0.05
80 min	20	57.80 ± 4.67	4.00	3.72	p < 0.01
90 min	11	59.09 ± 5.39	2.71	2.00	p > 0.05

IV. Oxygen saturation (SPO_2) - The pre and post induction SPO_2 of patients during surgery are summarized in table 4. During the period, the mean SPO_2 ranged from 98.56 (baseline) to 100.00% (after induction and 90 min). ANOVA revealed a significant effect of time on SPO_2 ($F=26.35$, $p<0.001$). Further, Dunnett's test revealed that the mean SPO_2 differed and was significantly ($p<0.01$) higher at all periods (after induction to 90 min) as compared to baseline.

Table 4: SPO_2 levels of patients during the surgery periods

Periods	N	Mean ± SD	Mean difference (from baseline)	q value	P value
Baseline	50	98.56 ± 0.50	Ref		
after induction	50	100.00 ± 0.00	1.44	14.72	P < 0.01
5 min	50	99.72 ± 0.50	1.16	11.85	P < 0.01
10 min	50	99.82 ± 0.44	1.26	12.88	P < 0.01
15 min	50	99.76 ± 0.59	1.20	12.26	P < 0.01
20 min	50	99.70 ± 0.65	1.14	11.65	P < 0.01
30 min	50	99.88 ± 0.33	1.32	13.49	P < 0.01
40 min	50	99.70 ± 0.61	1.14	11.65	P < 0.01
50 min	49	99.78 ± 0.55	1.22	12.36	P < 0.01
60 min	47	99.74 ± 0.61	1.19	11.92	P < 0.01
70 min	34	99.71 ± 0.29	1.35	12.43	P < 0.01
80 min	20	99.90 ± 0.31	1.34	10.35	P < 0.01
90 min	11	100.00 ± 0.00	1.44	8.84	P < 0.01

V. End tidal CO_2 ($ETCO_2$) - The post induction $ETCO_2$ of pediatric patients during surgery are summarized in table 5. During the period, the mean $ETCO_2$ ranged from 21.92 (after induction) to 35.18% (40 min). ANOVA revealed a significant effect of time on $ETCO_2$ ($F=18.78$, $p<0.001$). Further, Dunnett's test revealed that the mean $ETCO_2$ differed and was significantly ($p<0.01$) higher at all periods (10 min to 90 min) as compared to after 5 min.

Table 5: $ETCO_2$ levels of paediatric patients during the surgery periods

Periods	N	Mean ± SD	Mean difference (from baseline)	q value	p value
after induction	50	21.92 ± 2.83			
5 min	50	31.20 ± 1.37	ref		
10 min	50	32.82 ± 0.72	1.62	4.66	P < 0.01
15 min	50	32.96 ± 1.43	1.76	5.06	P < 0.01
20 min	50	33.16 ± 1.71	1.96	5.63	P < 0.01
30 min	50	33.90 ± 1.54	2.68	7.41	P < 0.01
40 min	50	35.18 ± 1.55	3.98	11.44	P < 0.01
50 min	49	34.49 ± 2.07	3.29	9.41	P < 0.01
60 min	47	34.62 ± 0.99	3.42	9.67	P < 0.01
70 min	34	33.82 ± 1.38	2.62	6.78	P < 0.01
80 min	20	33.85 ± 1.73	2.65	5.76	P < 0.01
90 min	11	34.18 ± 0.60	2.98	5.15	P < 0.01

DISCUSSION:

Pediatric sizes of I-gel became available in the latter half of 2009, extending the lower weight range from 30kg to 2kg. As with the adult sizes, the pediatric sizes have a non-inflatable cuff, a gastric channel, an integral bite block and a buccal cavity stabilizer. The first independent data on the use of the new pediatric sizes came from the Diemunsch, who presented an abstract on the device in October 2009 [3, 7]. This abstract reported on 50 insertions of the device in patients between 6 months and 14 years. Stability of the device and avoidance of intubation were seen as advantages.

The insertion of the I-gel was successful on the first attempt in 45 of the 50 patients (90%) and success rate was 100% on second attempt. In previous studies, the I-gel were successfully placed in one or two attempts in children, thus the success rate for inserting the device was 80%-100% on the first attempt and 100% after two attempts [3, 5-7]. Goyal *et al.;* in 2012 [8] also found success rate for first attempt was 95% for the I-gel and they concluded that paediatric size 2 I-gel was easy to insert as compared with same size PLMA and CLMA. According to our study the ease of insertion of I-gel in most of the patients was "easy" (88.0%) and only 12% of the patients require minor manipulations. These findings are consistent with previous studies showing easy insertion in 80%-95% patients [9, 10].

Regarding suitability of size according to weight, we found that in most of the patients it was found to be 'suitable" (76.0%). 24% patients require 1 size bigger I-gel, so the manufacturer`s recommendation according to the weight was found to be different with our study in 24% cases. The final quality of ventilation was "excellent" in all cases either by manipulating the device or after change of size if found to be inappropriate. This was also noticed by Bopp *et al.;* 2009 [3, 7] in there global study, involving 50 children undergoing ventilation using the I-gel paediatric device and found that the recommended size of the I-gel according to the weight was considered inadequate in 18 % of cases and a change was necessary in 16 %. Our study also shows similar results. In our study the Ryle's tube insertion was "easy" in all patients (100.0%) and average time of insertion of Ryle's tube was 4.34 ± 0.48 sec. Many previous studies also had similar outcomes regarding Ryle's tube insertion.

Beylacq *et al.;* 2009, Abukawa *et al.;* 2012 and Chauhan *et al.;* 2013 in their studies on children with the I-gel found that there was no gastric inflation and gastric tube insertion was achieved in all cases which is similar to our study [5, 6, 11]. Monclus *et al.;* 2010 [12] did pediatric I-gel evaluation under nuclear magnetic resonance (NMR). They introduced the I-gel under spontaneously ventilating patient, with subsequent placement of the drainage tube and noted that the I-gel was introduced without difficulty at first attempt. Drainage tubes were also introduced at first attempt. In our study we also we found that the insertion of the I-gel was successful on the first attempt in 90% of patients and success rate was 100% on second attempt and Ryle's tube insertion was "easy" in all patients (100.0%).

Hemodynamically patients were found to be stable throughout the surgery. Lower pressures can be explained by the use of propofol as an inducing agent and use of inhalational anesthetics during surgery. Although lowering of blood pressures is statistically significant but clinically it may not be of that much significance. SPO_2 remained between 98% to 100% throughout the operation. $EtCO_2$ remained between 28 to 38, statistically revealed that the mean $EtCO_2$ differed and was significantly ($p<0.01$) higher at all periods (10 min to 90 min) as compared to after 5 min but clinically it is not of much significance. No episodes of desaturation were found as seen in previous studies [13-15].

Helmy *et al.;* 2010 [16] study I-gel and classical laryngeal mask airway and found that the mean duration of insertion attempts was 15.6±4.9 seconds in the I-gel group while the number of insertion attempts was statistically insignificant between both the study groups, incidence of gastric insufflation was significantly more with LMA group (22.5%) vs. I-gel group (5%) (P=0.016) they concluded that both LMA and I-gel do not cause any significant alteration in the hemodynamic status of the patients, end tidal CO_2, and SPO_2.They also found that incidence of post-operative nausea and vomiting were less in I-gel group. We also found similar results in our study regarding insertion of the device as the mean duration of insertion in our study was 8.02 ± 2.45 sec. and we also found that the patients are hemodynamically stable with mean heart rate ranged from 105.68 to 114.52 beats/min and mean arterial pressure ranged from 70.25 (15 min) to 77.55 mmHg, had good ventilation and saturation (SPO_2) remained between 98% to 100% throughout the study.

Complications after removal of I-gel are very less only 4 patients had minor coughing (8.0%) and 1 had nausea and vomiting (2.0%). There is no episode of laryngospasm in any child and there is no trace of blood noted on the device after removal. These facts of our study are also supported by various other studies [17, 18].

CONCLUSION:

In our study we have found that I-gel insertion was easy, hemodynamically the patient was stable throughout the surgery, quality of ventilation and oxygenation was also found to be good and there were very few post-operative complications. Thus, we conclude that I-gel can be safely and effectively used in children undergoing elective surgery under general anaesthesia with spontaneous respiration.

REFERENCES:

1. Joshi GP, Inagaki Y, White PF, Taylor-Kennedy L, Wat LI, Gevirtz C et al. Use of the laryngeal mask airway as an alternative to the tracheal tube during ambulatory anesthesia. Anesth Analg. 1997 Sep; 85(3):573-7.
2. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia. 2005 Oct; 60(10): 1022-6.
3. Bopp C, Carrenard G, Chauvin C, Schwaab C, Diemunsch P. The I-gel in paediatric surgery: Initial series. In american Society of anesthesiologists (aSa) annual Meeting 2009 Oct (pp. 17-21).
4. 7th ed. Wokingham, UK: Intersurgical Ltd; 2009. I-gel User Guide.http://www.igel.com
5. Abukawa Y, Hiroki K, Ozaki M. Initial experience of the I-gel supraglottic airway by the residents in pediatric patients. J Anesth. 2012 Jun; 26(3):357-61.
6. Beylacq L, Bordes M, Semjen F, Cros AM. The I-gel®, a single-use supraglottic airway device with a non-inflatable cuff and an esophageal vent: an observational study in

children. Acta Anaesthesiologica Scandinavica. 2009 March; 53(3): 376–379.
7. Bopp C, Chauvin C, Schwaab C, Mayer J, Marcoux L, Diemunsch PL. I-gel en chirurgie pediatrique: serie initiale. 51 eme Congres National d′ Anesthesie et de Reanimation (SFAR) Paris, 23-26 September 2009. Ann Fr Anesth Reanim. 2009; 28.
8. Goyal R, Shukla RN, Kumar G. Comparison of size 2 I-gel supraglottic airway with LMA-ProSeal™ and LMA-Classic™ in spontaneously breathing children undergoing elective surgery. Paediatr Anaesth. 2012 Apr; 22(4):355-9.
9. Das B, Mitra S, Jamil SN, Varshney RK. Comparison of three supraglottic devices in anesthetised paralyzed children undergoing elective surgery. Saudi journal of anaesthesia. 2012 Jul; 6(3):224.
10. Uppal V, Fletcher G, Kinsella J. Comparison of the I-gel with the cuffed tracheal tube during pressure-controlled ventilation. Br J Anaesth. 2009 Feb; 102(2):264-8.
11. Chauhan G, Nayar P, Seth A, Gupta K, Panwar M, Agrawal N. Comparison of clinical performance of the I-gel with LMA proseal. J Anaesthesiol Clin Pharmacol. 2013 Jan; 29(1):56-60.
12. Monclus E, Garces A, Vassileva I, Sanchez A, Banchs R. Pediatric I-gel evaluation under nuclear magnetic resonance (NMR): 10AP1–5. European Journal of Anaesthesiology: 2010 June; 27 (47): 155.
13. Lehousse T, Foucher-Lezla A, Azau A, Monrigal JP, Granry JC. Pediatric I-gel™ Supraglottic Airway: Clinical Experience and Endoscopic Data.
14. Maharjan SK. I-gel for positive pressure ventilation. Journal of Nepal Medical Association. 2013 Jan 1; 52(189):255-9.
15. Taxak S, Bhardwaj M, Gopinath A. The i-gel™-A promising airway device for magnetic resonance imaging suite. Journal of anaesthesiology, clinical pharmacology. 2012 Apr; 28(2):263.
16. Helmy AM, Atef HM, El-Taher EM, Henidak AM. Comparative study between I-gel, a new supraglottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients. Saudi journal of anaesthesia. 2010 Sep; 4(3):131.
17. Asai T, Liu EH. I-gel, a new supraglottic airway. Masui. 2010; 59:794–7.
18. Singh I, Gupta M, Tandon M. Comparison of Clinical Performance of I-Gel™ with LMA—Proseal™ in Elective Surgeries. Indian journal of anaesthesia. 2009 Jun; 53(3):302.