

A prospective single-center observational study to assess the efficacy of the second-generation supraglottic airway device I-gel in laparoscopic surgeries in children

Rakhee Goyal^{1,2}, Rajat Chauhan¹, Rajan Anand¹, Manoj Goyal¹

¹Department of Anesthesia and Critical Care, Army Hospital Research and Referral, ²Department of Anesthesia and Critical Care, Madhukar Rainbow Children's Hospital, New Delhi, India

Abstract

Background and Aims: Supraglottic airways used in pediatric surgeries are associated with a lesser number of postanesthesia respiratory complications. However, there is limited literature on the use of i-gel for pediatric laparoscopic surgery. The aim of this study is to assess the adequacy of ventilation of i-gel for pediatric laparoscopic surgery and note any associated adverse event.

Material and Methods: This is a single-centered prospective observational study including 119 children, aged 6 months to 18 years, scheduled for laparoscopic surgery, during a 9-month period, in a tertiary care center. I-gel was used for positive pressure ventilation, and if the post-insertion oropharyngeal seal pressure was <25 cm H₂O, it was replaced with a tracheal tube. Adequacy of ventilation and adverse events were noted.

Results: Data from 102 cases were analyzed (17 cases excluded: tracheal intubation in 11; missing data in 6 cases). The mean oropharyngeal seal pressure was 34.2 ± 5.2 cm H₂O and mean airway pressure was 16.1 ± 2.4 cm H₂O. The adverse events included transient cough (10.7%), sore throat (4.9%), and desaturation (3.9%). There was no sign of respiratory distress during the recovery and no intervention was required in any child postoperatively.

Conclusion: I-gel provided adequate ventilation of the lungs in children undergoing laparoscopic surgery with no major adverse event.

Keywords: Child, complications, laparoscopy, pneumoperitoneum, safety, ventilation

Introduction

Supraglottic airway (SGA) devices such as classic LMA, ProSeal LMA, i-gel, Ambu, and so on have been used successfully in laparoscopic surgeries in adults. Their ventilation characteristics and safety profile are found to be comparable to endotracheal tubes (ETT).^[1-5] A large number of studies have assessed the use of SGAs for ventilation during surgery in children. A meta-analysis of 19 such studies by Luce *et al.*

found lesser perioperative respiratory complications such as postoperative desaturation, laryngospasm, cough, breath-holding, duration of postanesthesia care unit stay and so on with SGA in children.^[6] However, most studies have compared SGA to ETT in non-laparoscopic surgeries, and there is limited literature for its use in laparoscopic surgeries in children.^[7-11]

In laparoscopic surgery, the peak inspiratory pressure (PIP) is higher; therefore an SGA with higher glottic seal pressure is

Address for correspondence: Dr. Rakhee Goyal,
Department of Anesthesia and Critical Care, Madhukar
Rainbow Children's Hospital, New Delhi - 110 017, India.
E-mail: rakheegoyal@gmail.com

Access this article online

Quick Response Code:



Website:
www.joacp.org

DOI:
10.4103/joacp.JOACP_295_19

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

How to cite this article: Goyal R, Chauhan R, Anand R, Goyal M. A prospective single-center observational study to assess the efficacy of the second-generation supraglottic airway device I-gel in laparoscopic surgeries in children. *J Anaesthesiol Clin Pharmacol* 2020;36:20-4.

Submitted: 09-Sep-2019 **Revised:** 28-Oct-2019 **Accepted:** 28-Oct-2019
Published: 18-Feb-2020

likely to be suitable for ventilation. I-gel is a second-generation SGA with high oropharyngeal seal pressure (OSP). It has a soft, noninflatable cuff made of thermoplastic elastomer that provides anatomical seal without causing compression trauma. The gastric port in this device allows suctioning and prevents gastric insufflation, offering ease to surgical manipulation during laparoscopic surgery. A meta-analysis conducted by Maitra *et al.* showed that i-gel has significantly higher OSP compared to ProSeal LMA and can be used as an effective alternative in children.^[12]

The studies that used the tracheal tube for laparoscopic surgery showed that the PIP was <25 cm H₂O in all the cases.^[3,5,7] It was hypothesized that if the OSP of i-gel is >25 cm H₂O, adequate ventilation should be possible during laparoscopy. The present study was designed to test this hypothesis as the primary aim while the secondary aim was to note the perioperative adverse events associated with it.

Material and Methods

This is a single-centered prospective observational study, conducted in a tertiary care hospital from May 2017 to Jan 2018 with the approval of the hospital ethics committee (vide IRB number 57/2017 dated 25 Mar 2017). Written informed parental consent was taken for every child enrolled in the study. All the children scheduled for elective laparoscopic surgery were consecutively enrolled in the study. The children aged between 6 months and 18 years, ASA I-II, and BMI ≤ 30 kg.m⁻² were included in the study. The children with anticipated difficult airway, inadequately fasted (less than 6 h for solids, 4 h for breast milk, and 2 h for clear fluids), anticipated delayed gastric emptying (intestinal obstruction, pyloric stenosis, malrotation of gut, etc.), emergency surgery, and lower respiratory infection (purulent nasal discharge, productive cough, fever $>38^{\circ}\text{C}$, crackles or wheeze on auscultation) were excluded from the study. Children with recent but not ongoing upper respiratory tract infection (history of runny or blocked nose, cough, sneezing, mild fever) in the last 4 weeks were included in the study.

Inhalation induction was done with 8% sevoflurane and 50% oxygen and nitrous oxide, and intravenous access was secured. Propofol 2 mg.kg⁻¹, fentanyl 2–3 $\mu\text{g.kg}^{-1}$, atracurium 0.5 mg.kg⁻¹, and dexamethasone 0.1 mg.kg⁻¹ were given to all children. Standard monitoring included SpO₂, NIBP, ECG, nasopharyngeal temperature, and capnography. When the jaw was fully relaxed, an appropriately sized i-gel was inserted, a square wave capnography was confirmed, and i-gel secured with an adhesive tape. A suction catheter was inserted through the gastric channel, and it was suctioned at the beginning

and the end of surgery. Positive pressure ventilation was used on pressure control mode (fresh gas flow rate 2 L/min, inspiratory to expiratory ratio 1:2; PEEP 4 cm H₂O; airway pressure to generate 9–10 mL.kg⁻¹ tidal volume; age-appropriate respiratory rate to maintain end-tidal carbon dioxide 35–45 mmHg).

The oropharyngeal seal pressure of i-gel was checked by closing the expiratory valve of the circle system at the fresh gas flow of 3 L/min. The airway pressure at which the equilibrium was attained was noted as the OSP. If the OSP was <25 cm H₂O, the i-gel was replaced with a tracheal tube, and the case was excluded from the analysis.^[7]

Anesthesia was maintained with oxygen, air, sevoflurane 1 MAC, atracurium, Ringer's lactate, and intravenous paracetamol. The intra-abdominal pressure was set minimal as required but not >12 mmHg. The OSP was checked again, 2 min after the creation of pneumoperitoneum. If the OSP was found <25 cm H₂O at any time or an audible leak heard a gentle manipulation of the head and neck was done to minimize the leak. The ventilation was considered adequate when the peak airway pressure (to maintain a normal end-tidal carbon dioxide) was less than the OSP, else the i-gel was removed and replaced by a tracheal tube.

Neostigmine and glycopyrrolate were used to reverse the effects of neuromuscular blockade at the end of the surgery and i-gel was removed when the child was breathing adequately with <0.5 MAC sevoflurane. Any adverse events such as coughing, breath-holding, laryngospasm or desaturation, and blood on i-gel were noted.

All the children were observed for an hour by the anesthesia resident in-charge of the postanesthesia care unit (PACU) for sore throat, hoarseness of voice, and signs of respiratory distress such as tachypnea, tachycardia, desaturation, and wheeze or crackles on lung auscultation. They were reassessed every 8 h up to 24 h after discharge from PACU by the anesthesia resident on duty. A chest radiograph was done if any child presented with two or more of these signs. Any adverse event that persisted at the first assessment at 8 h and required intervention was considered a major adverse event.

Statistical analysis

In a pilot study of 20 cases based on the same protocol, the oropharyngeal pressure was 33 ± 5 cm H₂O. We calculated the sample size based on this standard deviation and absolute precision of 1 cm H₂O. The calculated sample size was 96 with a 95% confidence interval. Based on previous trends, the number of laparoscopic surgeries that could be done during the study period was assumed to be 125. Hence, we chose

to consecutively enroll all the patients scheduled for elective laparoscopic surgery so that after the dropouts and exclusions we have adequate sample size of 96.

The senior resident of the anesthesia team collected and compiled the data. The quantitative variable was described using mean and standard and qualitative variables using frequency and percentages. The association between two categorical variables was checked using a Chi-square test. One-way analysis of variance (ANOVA) was used for the association of quantitative variables with i-gel size after checking for Bartlett's test for equal variance. The data was analyzed using StataCorp. 2013 (Stata: Release 13. Statistical Software. College Station, TX: StataCorp LP).

Results

Figure 1 shows the flow diagram of patients enrolled in the study. A total of 130 children consecutively scheduled for laparoscopic surgery were enrolled in the study. Around 119 children met the inclusion criteria. In 11 children (10.7%), the i-gel was replaced with ETT because the seal pressure was <25 cm H₂O after insertion (8 cases -i-gel size 1.5; 3 cases -i-gel 2.5); and there was some missing data in six cases. The patient characteristics and the surgery details of 102 cases are listed in Tables 1 and 2, respectively. All the children adhered to fasting instructions but there were 21 children (20.5%) with a recent upper respiratory infection (URI). Size 2 i-gel was used in the maximum number of children (47%). Orchiectomy, hernia repair, and diagnostic laparoscopy were most common surgeries. The mean duration of pneumoperitoneum was 70.7 min ± 55.4 and that of anesthesia was 109.4 (83.9). The mean airway pressure was 16.1 ± 2.4 (range 14 to 20 cm H₂O). The peak airway pressure was the mean airway pressure plus the PEEP of 4 cm H₂O. The mean OSP was 34.2 ± 5.2 (≥40 cm H₂O in 25 cases; 24.5%). The error bar

diagram in Figure 2 shows the mean OSP, baseline and after pneumoperitoneum. There was a significant difference in the baseline OSP among different-sized i-gels (One-way ANOVA *P* value = 0.04). *Post hoc* analysis showed maximum difference between i-gel size 2 and i-gel size 1.5 (5.4; *P* value = 0.057). However, there was no statistically significant difference among different sizes for OSP pneumoperitoneum (one-way ANOVA *P* value = 0.25).

Table 1: Patient characteristics and details of i-gel

	n=102
Age (years)	4.9±3.7
Male:Female	73: 27
Weight (Kg)	19.4±10
Children with recent URTI	21 (13.2-29.7)
Duration of pneumoperitoneum (min)	70.7±55.4
Duration of anesthesia (min)	109.4±83.9
I-gel size	
Size 1.5	21 (13.2-29.7)
Size 2	48 (37.1-57.2)
Size 2.5	21 (13.2-29.7)
Size 3	12 (6.2-19.6)
I-gel replaced with ETT	11 (5.5-18.5)

Data expressed as mean ± Standard deviation or Confidence interval in brackets. URTI- upper respiratory tract infection. ETT- endotracheal tube

Table 2: Type of surgeries

Surgery	Number (%)	95% Confidence interval
Orchiopexy	27 (26.4)	18.2-36.1
Inguinal hernia repair	21 (20.5)	13.2-29.7
Diagnostic laparoscopy	18 (17.6)	10.8-26.4
Appendectomy	11 (10.7)	5.5-18.5
Pyeloplasty	8 (7.8)	3.4-14.8
Cholecystectomy	6 (5.8)	2.1-12.3
Ileo-anal pull through	3 (2.9)	0.6-8.4
Nephrectomy	3 (2.9)	0.6-8.4
Splenectomy	2 (1.9)	0.2-6.9
Oophorectomy	2 (1.9)	0.2-6.9
Ovarian cystectomy	1 (0.9)	0.02-5.3

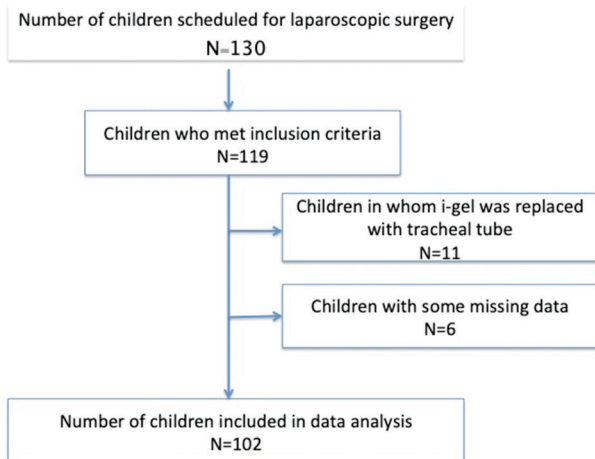


Figure 1: Flow chart of the study patients

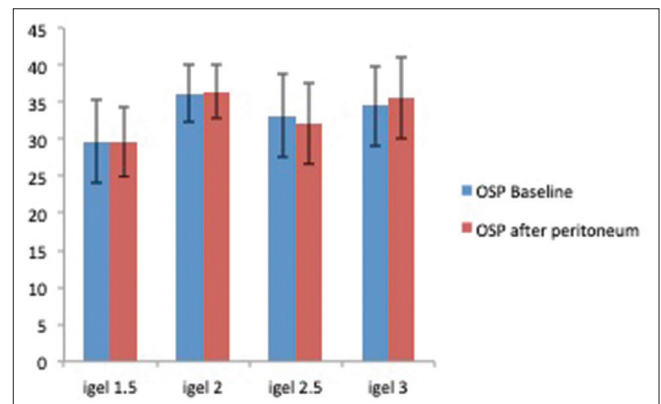


Figure 2: Error bar diaphragm showing the mean oropharyngeal pressure at baseline and after pneumoperitoneum for different-sized i-gels

Table 3 shows the seal pressure, airway pressure, mean arterial pressure, heart rate, and SpO₂.

Some of the cases required Trendelenburg or reverse-Trendelenburg position, and in some cases, the head had to be turned to one side for the ease of manipulation of laparoscopy instruments. The i-gel was not displaced during a change of position in any case.

Five children indicated soreness in the throat that subsided within 4 h (duration of i-gel >2 h in four children, and one child had a preoperative sore throat). A sore throat could not be identified in 28 children. These children were aged between 6–15 months. Two children had hoarse cry immediately on waking up but it subsided in an hour in both. Eleven children coughed after the device was removed but they did not cough again later. Blood on the device was not found in any case in the study. Four children had partial laryngospasm with transient desaturation (SpO₂ up to 80%) after removal of the i-gel. One of them had a history of recent URI. All of them responded well to positive pressure breaths with 100% oxygen. There was no sign of respiratory distress in any case. All the children were shifted to their rooms without any delay due to an adverse event.

Discussion

Tracheal intubation is the gold standard for ventilation and securing of the airway in children^[13] but recent studies have shown that the perioperative respiratory complications are lesser with the use of supraglottic airway devices.^[6] This study explored the possibility of using i-gel, a second-generation SGA for laparoscopic surgery in children aged 6 months to 18 years. Among the 102 patients analyzed, the mean OSP was 34.2 ± 5.2 , the PIP was 16.1 ± 2.4 cm H₂O, and the ventilation was adequate. In 11 cases, the OSP was not up to the desired level and the device was replaced with a tracheal tube. There was no major adverse event in any case, and all the children were discharged from the hospital in time. There were 20.5% children with recent preoperatively URI but they did not have any respiratory complications except transient

desaturation at extubation, in just one of them. This study does not prove that tracheal tubes should be replaced with i-gels but merely suggests that i-gel can be a suitable device for ventilation during pediatric laparoscopic surgeries. The authors recommend that in the patients where the baseline seal pressure is not adequate, a tracheal tube must be placed before the pneumoperitoneum.

During pneumoperitoneum in children, the diaphragm is elevated, functional residual capacity is reduced, and there is a ventilation-perfusion mismatch in the Trendelenburg position.^[14-16] In addition, in newborns and smaller infants, there is increased systemic absorption of carbon dioxide as the peritoneal absorption surface per unit of weight is high.^[17] To maintain normocarbida in this scenario, the PIP and respiratory rate are required to be higher. Moreover, i-gel can provide a good glottic seal that allows higher PIP. When the OSP is more than the PIP, there should not be any significant airway leak and adequate ventilation can be achieved. In this study, the OSP was up to 40 cm H₂O in 24.5% cases.

Dave *et al.* studied 30 children, 10–30 kg weight, scheduled for short laparoscopic procedures and found adequate ventilation with ProSeal LMA in 28 patients. There was no evidence of any regurgitation or sore throat in any child. They did not measure the seal pressure but estimated the ventilation based on SpO₂ and etCO₂, and found it to be satisfactory. The peak airway pressures after pneumoperitoneum and Trendelenburg position were 20.67 ± 4.44 cm H₂O⁴.

Sinha *et al.* compared ProSeal LMA with a tracheal tube for short laparoscopic procedures in 60 children 6 months to 8 years. They found OSP >25 cm H₂O with ProSeal LMA and PIP <25 cm H₂O in all cases. There was no regurgitation or pulmonary aspiration in any case but blood on the device was seen in three cases.^[3]

A recent study by Kohli *et al.* compared i-gel with a tracheal tube in 80 children, 2–8 years of age, for <1h duration laparoscopic procedures and found comparable adequacy of ventilation. The peak airway pressure was <20 cm H₂O in all the cases. There was no sore throat or cough with i-gel in any child.^[7]

The authors observed that the use of neuromuscular blockers helps to maintain the glottic seal and thereby adequate ventilation throughout the surgery. Moreover, the pharyngeal muscle tone is maintained steady at all stages of surgery and prevents the displacement of the SGA device.

This study is limited by its observational nature, lack of a control group, and been conducted in a single center. Size 1

Table 3: Oropharyngeal and airway pressures; Vital parameters

Parameters	Results ± standard deviation
Oropharyngeal pressure baseline (cm H ₂ O)	34.2±5.2
Oropharyngeal pressure after pneumoperitoneum (cm H ₂ O)	34.2±5.3
Mean airway pressure (cm H ₂ O)	16.1±2.4
Mean arterial pressure (mmHg)	67.1±3.5
Heart rate (beats per min)	103.4±15.9
SpO ₂ (%)	99±2.1
Temperature (degree celcius)	36.8±2.2

and 4 were not used in the study, as extremes of body weight were not included. The sample size used in this study was based on the ventilation efficacy of i-gel. Hence, it would not be appropriate to make any conclusion regarding the safety of the device. This is a preliminary report and future work with a larger sample size would be able to address the safety concerns.

In conclusion, the i-gel may be used to provide adequate ventilation of the lungs in children undergoing laparoscopic surgery.

Acknowledgments

The authors sincerely thank Dr Arun Kumar Yadav, Associate Professor (Community Medicine), Armed Forces Medical College, Pune, India for his assistance in the statistical analysis of this study.

Disclosures

The study was approved by the Institutional Ethics Committee.

Ethics

The study was approved by the hospital ethics committee, Army Hospital Research and Referral, New Delhi, India dated 26 Mar 2017.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Yu SH, Beirne OR. Laryngeal mask airways have a lower risk of airway complications compared with endotracheal intubation: A systematic review. *J Oral Maxillofac Surg* 2010;68:2359-76.
2. Maltby JR, Beriault MT, Watson NC, Liepert D, Fick GH. The LMA-ProSeal is an effective alternative to tracheal intubation for laparoscopic cholecystectomy. *Can J Anaesth* 2002;49:857-62.
3. Lu PP, Brimacombe J, Yang C, Shyr M. ProSeal versus the classic laryngeal mask airway for positive pressure ventilation during laparoscopic cholecystectomy. *Br J Anaesth* 2002;88:824-7.
4. Sharma B, Sood J, Sahai C, Kumra VP. Efficacy and safety performance of ProSeal™ laryngeal mask airway in laparoscopic surgery: Experience of 1000 cases. *Indian J Anaesth* 2008;52:288-96.
5. Saraswat N, Kumar A, Mishra A, Gupta A, Saurabh G, Srivastava U. The comparison of ProSeal laryngeal mask airway and endotracheal tube in patients undergoing laparoscopic surgeries under general anaesthesia. *Indian J Anaesth* 2011;55:129-34.
6. Luce V, Harkouk H, Brasher C, Michelet D, Hilly J, Maesani M, *et al.* Supraglottic airway devices vs tracheal intubation in children: A quantitative meta-analysis of respiratory complications. *Paediatr Anaesth* 2014;24:1088-98.
7. Sinha A, Sharma B, Sood J. ProSeal as an alternative to endotracheal intubation in pediatric laparoscopy. *Paediatr Anaesth* 2007;17:327-32.
8. Dave NM, Iyer HR, Dudhedia U, Makwana J. An evaluation of the ProSeal laryngeal mask airway in paediatric laparoscopy. *J Anaesth Clin Pharmacol* 2009;25:71-3.
9. Ozdamar D, Güven BH, Tokar K, Solak M, Ekingen G. Comparison of the effect of LMA and ETT on ventilation and intragastric pressure in pediatric laparoscopic procedures. *Minerva Anesthesiol* 2010;76:592-9.
10. Greif R, Theiler L. The use of supraglottic airway devices in pediatric laparoscopic surgery. *Minerva Anesthesiol* 2010;76:575-6.
11. Kohli M, Wadhawan S, Bhadoria P, Ratan SK. Comparative evaluation of I-gel vs. endotracheal intubation for adequacy of ventilation in pediatric patients undergoing laparoscopic surgeries. *J Anaesthesiol Clin Pharmacol* 2019;35:30-5.
12. Maitra S, Baidya DK, Bhattacharjee S, Khanna P. Evaluation of i-gel™ airway in children: A meta-analysis. *Pediatr Anaesth* 2014;24:1072-9.
13. Mhamane R, Dave N, Garasia M. Use of Microcuff® endotracheal tubes in paediatric laparoscopic surgeries. *Indian J Anaesth* 2015;59:85-8.
14. Tobias JD. Anaesthesia for minimally invasive surgery in children. *Best Pract Res Clin Anaesthesiol* 2002;16:115-30.
15. Hansen TG, Hennenberg SW, Lerman J. General abdominal and urologic surgery. In: Cote CJ, Lerman J, Anderson BJ, editors. *A Practice of Anesthesia for Infants and Children*. 6th ed. Philadelphia: Elsevier; 2019. p. 669-89.
16. Sood J. Anaesthesia in Laparoscopic Surgery. *Anaesthesia for Laparoscopy in Paediatric Patients*. 1st ed. India: Jaypee; 2007. p. 167-76.
17. McHoney M, Corizia L, Eaton S, Kiely EM, Drake DP, Tan HL, *et al.* Carbon dioxide elimination during laparoscopy in children is age dependent. *J Pediatr Surg* 2003;38:105-10.