Comparative evaluation of I-gel vs. endotracheal intubation for adequacy of ventilation in pediatric patients undergoing laparoscopic surgeries

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Abstract

Background and Aims: The use of newer supraglottic devices has been extended to laparoscopic procedures. We conducted this study to compare and evaluate the efficacy of these two devices in pediatric laparoscopic surgeries.

Material and Methods: Eighty children, 2–8 years of age, scheduled for elective short laparoscopic procedures were randomly allocated to the I-gel or endotracheal tube (ETT) group. Standard anesthesia protocol was followed for inhalational induction. I-gel or ETT was inserted according to the manufacturer’s recommendations. Ventilation was set with tidal volume 10 ml/kg and a respiratory rate of 16/min. Carboperitoneum was achieved up to an intra-abdominal pressure of 12 mmHg.

Statistical Analysis: The primary outcome variable was adequacy of ventilation (peak airway pressure, end-tidal CO₂, minute ventilation, and S₉O₂). These variables were recorded after securing airway, after carboperitoneum and desufflation of the peritoneal cavity. The oropharyngeal leak pressures were also noted. Statistical analysis was done using SPSS software version 17.0. P <0.05 was considered statistically significant.

Results: No significant difference was observed in the heart rate or mean arterial pressure. There was a significant increase in the P₈CO₂ and peak airway pressure after creation of carboperitoneum. There was significant increase in minute ventilation in both groups after creation of carboperitoneum.

Conclusion: To conclude, I-gel is comparable to endotracheal intubation in terms of adequacy of ventilation. The increase in peak airway pressures is less with I-gel. In addition, postoperative complications are fewer with I-gel.

Keywords: Airway management, hemodynamics, intratracheal intubation, laparoscopy, laryngeal mask, respiration

Introduction

Controlled ventilation with an endotracheal tube (ETT) has been the gold standard in pediatric laparoscopic surgeries and is preferred by most anesthesiologists.

The improved safety in the form of gastric drainage, and hence, prevention from aspiration as well as better seal designed in the newer supraglottic devices have enabled their use in laparoscopic procedures as well.

I-gel is a relatively new noninflatable supraglottic device that mirrors the laryngeal anatomy in design. The cuff is made up of a thermoplastic elastomer (styrene ethylene butadiene). It has a rigid bite-block and an esophageal vent through which a gastric tube can be passed, hence broadening its application to controlled ventilation in laparoscopic surgeries. Pediatric I-gel is available since 2009 with the available sizes being 1.0, 1.5, 2.0 and 2.5 for neonates 2–5 kg, infants 5–10 kg, small children 10–25 kg, and large children 25–35 kg, respectively.
Maharjan, in 2012, compared hemodynamics and ventilation parameters of I-gel and laryngeal mask airway with tracheal intubation during laparoscopic surgery in adults. This study concluded that I-gel produced the least hemodynamic stress response while both supraglottic devices had acceptable ventilation parameters during laparoscopic surgery.[4] Suhitharan also conducted a similar study in 2013 comparing I-gel to LMA Supreme.[5] However, to our knowledge, there is a paucity of studies comparing I-gel and endotracheal intubation in pediatric patients undergoing laparoscopic surgeries. Hence, we conducted this study to compare and evaluate the efficacy of these two devices in pediatric laparoscopic surgeries. Efficacy is the ability to produce a desired or intended result which in our case was maintaining adequate ventilation parameters during laparoscopic surgery.

Material and Methods

After obtaining approval from Institutional Ethical Committee, and registration in Clinical Trials Registry of India (CTRI/2017/05/00849), a prospective randomized controlled study was conducted in the Department of Anaesthesiology and Intensive Care over a period of 1 year.

The sample size was calculated using preliminary data, i.e., the results obtained from the parent article,[6] using SPSS Statistics for Windows, Version 17.0 (SPSS Inc., Chicago, USA). Considering an alpha error of 0.05 and a power of study at 90%, the sample size calculated was 80. The primary parameter was adequacy of ventilation (peak airway pressure, end-tidal CO₂, minute ventilation, and SpO₂).

Patients were randomly allocated by computer generated random number table to one of two groups, I-gel or ETT, comprising 40 patients each.

Children between the ages of 2 and 8 years of either sex, ASA grade I and II, undergoing elective laparoscopic surgery with controlled ventilation of estimated duration of ≤1 h in the pediatric surgery operation theatre were included. Patients with known/predicted difficult airway, history of lung disease, conditions with high risk of aspiration (full stomach, previous gastric surgery, gastroesophageal reflux disease, hiatus hernia), and obesity were excluded.

Written informed consent was taken from the patient’s parents/guardian and assent was taken from children above the age of 7 years in a language they understood.

All patients were kept nil per orally as per ASA guidelines for their age. Premedication with syrup promethazine 0.5 mg/kg was given orally 1 h before induction of anesthesia. Standard anesthesia protocol was followed. After attaching standard monitoring devices (ECG, NIBP, SpO₂), baseline vital parameters were recorded. Anesthesia was induced by inhalation of sevoflurane ≤8% + Oxygen + Nitrous oxide (50:50). After induction, appropriate size IV access was secured. All patients were given fentanyl 2 µg/kg IV. After ensuring adequacy of ventilation, muscle relaxation was achieved with vecuronium 0.1 mg/kg IV. Mask ventilation for 3 min was done, and the prechecked and prepared airway device (I-gel or ETT) of appropriate size was inserted according to the manufacturer’s recommendations.

Ease of insertion of both airway devices was assessed by the time taken for insertion and number of attempts. Any complications such as bronchospasm, desaturation, or trauma were noted.

- Time of insertion was defined as the time taken from holding the airway device to the first square-shaped capnograph tracing including the number of attempts
- The number of attempts required for successful insertion was noted. Two attempts at insertion were allowed (including change in size and any manoeuvre required) and the respective times were noted as T1 and T2. Effective time was calculated by adding T1 and T2. If the SpO₂ fell below 94%, the patient’s lungs were ventilated with 100% oxygen till the SpO₂ increased above ≥94%. The time of ventilation was not a part of the effective airway time. If placement failed after two attempts, the insertion was recorded as failed insertion and airway was secured with appropriate size alternate airway device and was excluded from further statistical analysis.

Hemodynamic parameters namely heart rate and mean arterial pressure were noted after airway insertion for every minute for the next 5 min. Subsequently, end-tidal CO₂, SpO₂, minute ventilation, peak airway pressure, and hemodynamic parameters were measured at regular intervals.

After ensuring placement, a Ryle’s tube of appropriate size was inserted into the drain tube of I-gel. Similarly, in patients with ETT in place orogastric tube was inserted. Number of attempts for both were recorded.

Anesthesia was maintained with oxygen + nitrous oxide (50:50) and sevoflurane (1–2%), and neuromuscular blockade was maintained with vecuronium in both groups. Ventilation was set with tidal volume 10 ml·kg⁻¹ and respiratory rate of 16/min with an I: E ratio of 1:2. Carboponiteneum was achieved up to an intra-abdominal pressure of 12 mmHg.

Ororharyngeal leak pressures in I-gel were recorded before and after carboponiteneum. The minimum fresh gas flow
was maintained at 3 l/min. The adjustable pressure limiting valve (APL) of the circle system was closed and the canister was bypassed. Oropharyngeal pressure was measured when an audible gas leak was heard over the trachea using a stethoscope and when the airway pressure stabilized in the pressure measuring manometer attached to the side stream capnograph port. Airway pressure was not allowed to exceed 40 cmH2O.

Hemodynamic parameters (MAP and PR), P_e CO$_2$, peak airway pressure (mmHg), SpO$_2$, and minute ventilation were recorded after securing airway (baseline), soon after carboperitoneum, and after desufflation of the peritoneal cavity. Ventilation was considered suboptimal if P_e CO$_2$ was >45 mmHg, and minute ventilation was adjusted with increase in respiratory rate to optimize the P_e CO$_2$. If the P_e CO$_2$ was >45 mmHg despite increasing the minute ventilation, then the device was replaced by an appropriate size ETT and the case was excluded from statistical analysis. Oxygenation was maintained at SpO$_2$ ≥94%,[7] and considered suboptimal if it fell <94% despite increasing minute ventilation or increasing FiO$_2$ to 1, and was similarly replaced by appropriate size ETT and the case was excluded from statistical analysis. Duration of carboperitoneum and total anesthesia time were recorded. Antiemetic ondansetron 0.1 mg/kg IV was given and paracetamol suppository 30–40 mg/kg was placed for postoperative analgesia.

At the end of the surgical procedure, anesthesia was discontinued and the residual effect of muscle relaxant was reversed with glycopyrrolate 10 μg/kg IV and neostigmine 60 μg/kg IV and the ETT or I-gel was removed. Complications during removal (laryngospasm, bronchospasm, vomiting, presence of blood on device) and postoperatively (sore throat or cough immediately and after 24 h) were recorded.

Statistical analysis
1. P < 0.05 was considered statistically significant
2. Qualitative data was analyzed using Chi-square or Fisher’s exact test
3. Quantitative data between groups (hemodynamic parameters after insertion of device) was analyzed using Student’s t-test or Mann–Whitney U-test
4. Quantitative data within groups (end-tidal CO$_2$, minute ventilation, hemodynamic parameters, SpO$_2$, and peak airway pressure) was analyzed using paired t-test or Wilcoxon signed rank test.

Results
There were no statistically significant differences in demographic characteristics between the groups [Table 1].

Table 1: Demographic profile

| Age (in years) | ETT n | Percentage | I-gel n | Percentage |
|---------------|-------|------------|---------|------------|
| 2-4           | 19    | 47.5%      | 17      | 42.5%      |
| 4.1-6         | 4     | 10.0%      | 4       | 10.0%      |
| 6.1-8         | 17    | 42.5%      | 19      | 47.5%      |
| Total         | 40    | 100%       | 40      | 100%       |

| Weight distribution (Kg) |
|--------------------------|
| Mean                     | 16.2 | 18.6 |
| ±SD                      | 8.3  | 7.7  |
| P-value                  | 0.091|

| Sex distribution |
|------------------|
| Gender           | ETT n | Percentage | I-gel n | Percentage |
| Male             | 27    | 67.5%      | 30      | 75.0%      |
| Female           | 13    | 32.5%      | 10      | 25.0%      |
| Total            | 40    | 100%       | 40      | 100%       |
| P-value          | 0.229|

Table 2: Ease of device insertion

| No. of attempts | ETT n | Percentage | I-gel n | Percentage | P   |
|-----------------|-------|------------|---------|------------|-----|
| 1               | 39    | 97.5%      | 31      | 77.5%      | 0.003|
| 2               | 1     | 2.5%       | 9       | 22.5%      |     |
| Total           | 40    | 100%       | 40      | 100%       |     |

Number of attempts
The first attempt success rate for ETT and I-gel was 97.5% and 77.5%, respectively [Table 2]. In 1 case in the ETT group and in 9 cases in the I-gel group, the device had to be replaced with different size of the same group. In the I-gel group, 8 patients out of 9 were below the age of 4 years. Accordingly, mean insertion time for the ETT (19.8 ± 8.5 s) was found to be lower than that of I-gel (22.4 ± 13.0 s), which was statistically insignificant.

The gastric tube placement was 100% successful in both the groups. No difficulty was encountered during the insertion of the gastric tube.

The increase in PR from preoperative values was 9.0% for the ETT group and 2.4% for the I-gel group at 1 min. The increase in MAP from preoperative values was 2.9% for the ETT group and 3.0% for the I-gel group at 1 min [Table 3]. The PR and MAP decreased to values below preoperative at 5 min. Paired t-test was used to analyze the heart rate and mean arterial pressure within the groups, and Student’s t-test was used to analyze the same between the two groups.
Adequacy of ventilation

There was a significant increase in the $P_{a}CO_{2}$ after creation of carperitoneum in both the groups [Table 4]. There was no significant difference between the values of both the groups.

There was a significant increase in the peak airway pressure after creation of carperitoneum in both the groups [Table 5]. There was a significant difference in the increase in peak airway pressure between the two groups, the increase being more in the ETT Group.

No significant difference in oxygen saturation was seen between the two groups. In no case did the device require replacement by an ETT due to suboptimal ventilation.

There was a significant increase in minute ventilation in both groups after the creation of carperitoneum. There was no significant difference between the minute ventilation before creation of carperitoneum and after desufflation of peritoneal cavity. The respiratory rate was increased in some children, namely 11 in the ETT group and 10 in the I-gel group after creation of carperitoneum to keep the end-tidal $CO_{2}$ levels below 45 mmHg. The respiratory rate was increased from 16 to 22 per min in all cases.

There was an increase in oropharyngeal leak pressure after the creation of carperitoneum, which was statistically significant [Table 6].

Complications such as cough were seen immediately in 4 cases in the ETT group which was statistically significant but was not sustained for 24 hours. No cases of cough were observed in the I-gel group. No cases of sore throat were observed in either groups.

Furthermore, it was observed that as age increased, the requirement to increase minute ventilation (which was increased by respiratory rate) decreased. The tidal volume was kept constant and respiratory rate was increased from 16 per min to 22 per min. As age increased the need to increase the minute ventilation to maintain normocapnia decreased [Table 7]. This relationship was seen by Pearson’s coefficient of correlation.

Discussion

Changes in pulmonary mechanics are of particular concern in children undergoing laparoscopy as they have low functional residual capacity, which is further compromised with carperitoneum. Hence, tracheal intubation has been considered ideal for airway management in pediatric laparoscopic surgery.

Supraglottic airway devices, such as I-gel, are also being used for airway control during spontaneous and controlled ventilation under general anesthesia.

We observed that the first attempt success rate for insertion of ETT and I-gel was 97.5% and 77.5%, respectively. In addition, difficulty was observed in the insertion of I-gel mainly in young children. This is mainly due to poor seal and compression of glottic structures. Technical difficulties with supraglottic devices increase with decreasing age.

Accordingly, the mean insertion time for ETT was found to be lower than that of I-gel but this was not statistically significant. This is in contrast to a study conducted by Abukawa et al. on pediatric population in 2012 where the first attempt insertion rates for size 1.5 and size 2 I-gel were found to be 99% and 94%, respectively. It is in agreement with Sinha et al. who in 2007 in their study on pediatric population observed that in the tracheal tube group all patients could be successfully intubated in the first attempt; however, in the Proseal laryngeal mask airway (PLMA) group, only 88% of the patients could have the device placed in the first attempt and 12% required a second attempt.

The gastric tube placement was 100% successful in both the groups in our study. This is consistent with the observations of Richez et al., where the gastric tube was successfully inserted in all cases. This insertion of gastric drain prevents gastric insufflation. This helps in decreasing nausea and vomiting postoperatively.

We found no significant difference in the rise in heart rate or mean arterial pressure between the groups on device insertion, though the increase was less in group I-gel. Thus, more stable hemodynamics were observed with I-gel. Similarly, it was reported by Sinha et al. in a study conducted among

Table 3: Hemodynamic changes

|        | Pre-op | 1 min | 2 min | 3 min | 4 min | 5 min |
|--------|--------|-------|-------|-------|-------|-------|
|        | PR     | MAP   | PR    | MAP   | PR    | MAP   | PR    | MAP   | PR    | MAP   |
| ETT    | Mean   | 95.3  | 65.1  | 103.9 | 67.0  | 101.1 | 66.1  | 99.6  | 63.5  | 95.9  | 64.6  | 94.8  | 64.3  |
|        | ±SD    | 19.1  | 9.4   | 17.9  | 9.5   | 19.0  | 9.7   | 19.0  | 13.4  | 19.3  | 9.7   | 18.9  | 9.7   |
| I-Gel  | Mean   | 86.2  | 69.0  | 88.3  | 71.2  | 86.6  | 70.6  | 84.4  | 69.8  | 84.1  | 69.4  | 84.2  | 69.2  |
|        | ±SD    | 13.1  | 13.2  | 16.9  | 14.2  | 16.4  | 13.9  | 15.6  | 14.0  | 16.0  | 13.9  | 16.3  | 14.0  |
children that the changes in hemodynamic parameters were not statistically significant when intergroup comparison between PLMA and ETT groups was made. Similarly, Maharjan in 2012 observed that hemodynamic perturbations were maximum with tracheal intubation and moderate with laryngeal mask airway whereas stable hemodynamics were observed with I-gel.\cite{4}

In our study, there was a significant increase in the end-tidal CO$_2$ after creation of the carboperitoneum in both the groups. The increase in end-tidal CO$_2$ was managed by increasing the respiratory rate from 16 to 22 per min in all cases, hence, increasing the minute ventilation in these patients. In addition, there is a negative correlation between age and the difference in minute ventilation after creation of carboperitoneum, i.e., as the age increased the need to increase the minute ventilation to maintain normocapnia after carboperitoneum decreased. This is in agreement with Sinha \textit{et al.} who in 2007 conducted a study comparing the ventilatory efficacy of PLMA and endotracheal intubation in children undergoing elective laparoscopic procedures. In their study, 5 patients in the group with ETT and 6 patients in the group with PLMA had suboptimal ventilation, i.e., the end-tidal CO$_2$ increased above 45 mmHg. The respiratory rate was increased to increase the minute ventilation. These changes were not significant between the two groups.

We observed a significant increase in the peak airway pressure (mmHg) after creation of carboperitoneum in both the groups. Moreover, group I-gel had a significantly lesser increase in peak airway pressure. This is similar to what Sinha \textit{et al.} observed in children that there was a significant change in PIP (cmH$_2$O) in the endotracheal tube group as well as the PLMA group after carboperitoneum; however, the changes were not significantly different between the groups.

There was an increase in oropharyngeal leak pressure in Group I-gel after the creation of carboperitoneum, which was statistically significant. Thus, it was seen that the seal improved after insufflation of the peritoneal cavity.

In contrast, in a study comparing the PLMA and I-gel during gynecological laparoscopy conducted by Jeon \textit{et al.} in 2012, it was found that oropharyngeal leak pressures did not vary significantly between or within groups 15 min after CO$_2$ insufflation.\cite{13} The difference may be attributed to the more compliant tissues in the pediatric age group.

Cough was the only complication recorded in the ETT group. It was present in the immediate postoperative period in 4 cases but was not sustained for 24 hours. No other complications were recorded. These were observations made during the study but sample size was not calculated. Sinha \textit{et al.} also reported that the incidence of cough at extubation in children was significantly higher in the group with ETT compared to the PLMA group. In addition, blood on device was only seen in three patients of the PLMA group. In a meta-analysis by Luce \textit{et al.} in 2014 on the respiratory complications between supraglottic airway devices and tracheal intubation, it was found that during recovery from anesthesia, the incidence of desaturation, laryngospasm, cough, and breath holding was lower when laryngeal mask airway was used, which is consistent with our study.\cite{14}

We may conclude that I-gel is a good alternative device to ETT for airway management in pediatric laparoscopic procedures with controlled ventilation as it is comparable in...
terms of adequacy of ventilation. Furthermore, postoperative complications were observed to be fewer with I-gel.

However, a study comparing the two airway devices in pediatric laparoscopic surgeries, especially with respect to hemodynamics and complications may be conducted as the sample size of our study was not selected according to these parameters. Moreover, a study dividing age groups into smaller groups may be considered.

We also observed that as age of the patients increased, the need to increase the minute ventilation to maintain normocapnia decreased. This may be evaluated in future studies.

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**Conflicts of interest**
There are no conflicts of interest.

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