Comparison of hemodynamic and Ventilator parameters with i-gel vs endotracheal tube in patients for laparoscopic cholecystectomy

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Abstract
Laparoscopic surgery or minimal invasive surgery is an evolving surgical specialty in view of number of advantages like minimal bleeding, small incision, less surgical scar and short recovery time. It is done with insufflation of carbondioxide in the peritoneal cavity leading to increased abdominal pressure, raised carbon-dioxide levels, hemodynamic changes or lung aspiration. (1) Till date cuffed endotracheal tubes are used to secure the airway and adequate control of airway pressures but the airway manipulation during laryngoscopy and ventilation leads to sympatho-adrenal axis stimulation that can cause increase in heart rate, blood pressure, increased myocardial contractility, increased myocardial oxygen demand, myocardial ischemia or infarction, increased intracranial pressures or bronchospasm. To combat these effects we used laryngeal mask airway to secure the airway and control of ventilation during laparoscopic cholecystectomy.

Methodology: A total of 80 patients of ASA-1 &2 selected for this double blind, prospective, randomised study. They were divided into two groups; group I and group E, of 40 each. Group-I was managed by LMA (i-gel) and Group-E by endotracheal cuffed tube. A detailed pre-anesthesia check up done for all the patients and informed consent taken. All patients who fulfilled the inclusion criteria were kept nil orally for six hours before the surgery and anaesthesia. Pre-medication given with cap pantoprazole 40mg night before the surgery and at 6.0am on the day of surgery. In the operation theatre after recording the baseline vital parameters all patients induced and airway device was used as per their group. Any changes in the heart rate, blood pressure, airway pressures recorded and compared. Incidence of post-operative throat discomfort or Sore throat also noted down.

Results: The number of attempts taken to place the i-gel or endotracheal tube was not significant but the duration of time to place the i-gel v/s ETT was quite less.....14.98 v/s 19.23 sec ( p-value =< 0.05). A significant increase in the heart rate and blood pressure at the time of endotracheal intubation in group- E patients from a baseline of 74.10 to 82.30 compare to group-I that varied from 74.10 to 75.15 maximum(p-value <0.05). The mean blood pressure was 123.33 mmhg in group I and 124.10mmhg in group E.A significant rise in Systolic and diastolic Blood Pressure is seen at at 1 and 5 minutes in group E and a similar trends seen in extubation. (p --0.05). No significant differences recorded in the mean airway pressure in both the groups before, during and after the pneumoperitoneum (p-- >0.05).

Conclusion: Use of i-gel-LMA is better tolerated by the patient in terms of hemodynamic stability, airway pressures and post-operative comfort.

Keywords: Laparoscopy, laryngeal mask airway, cholecystectomy.
Introduction
Laparoscopic cholecystectomy is one of the most commonest surgery done with general anesthesia and endotracheal intubation was the gold standard for providing safe glottis seal.\(^{(1,2)}\) Airway handling while laryngoscopy and endotracheal intubation, Creation of Pneumoperitoneum and reverse trendelenberg position makes lot of hemodynamic changes and changes in airway pressures that can lead to laryngospasm, bronchospasm, hypoxia, hypercarbia or arrhythmias.\(^{(3,4,5)}\) To avoid all such problems we used supraglottic airway device, a laryngeal mask airway -i-gel and compared the effects\(^{(6)}\).

Material and Methods
After the hospital ethics committee clearance, A Prospective, randomized study done on 80 patients of ASA class 1 & 2. Randomisation was done with www.randomization.com. Patients were divided into two groups of forty each. Sample size was calculated based on previous study done by jigisha et al in 2015 and a minimum of 30 patients were sufficient in each group to provide power of 90% to detect differences between studies. Group I was given i-gel for the surgery and group E was managed with Endotracheal tube. Statistical results were analysed by chi-square or Fischer exact test or student t-test. A p-value of less than 0.05 was considered significant. Patients with neuropsychiatric disturbances, OSA, Pregnant patients, patients with gastroesophageal reflux disease or full stomach patients were excluded from the study. Informed Consent was taken from all the patients included in the study. Pre-anesthesia check-up done for all the patients day before the surgery. Patients kept nil orally six hours before the surgery and tablet zolpidem 10mg with pantoprazole 40mg given night before the surgery at 10.00pm. On arrival to the operation table baseline vital parameters recorded. Dose of prophylactic antibiotic given with Inj. Cefuroxime 1.5 gm IV 30 mins before the surgery. Anaesthesia technique was similar to all the patients. After preoxygenation for three minutes, induction done with fentanyl 2.0mcg/kg, Propofol 1-2mg/kg IV and Rocuronium 0.6mg/kg IV after confirming adequate bag and mask ventilation. Airway managed either with i-gel or Endotracheal tube and anaesthesia maintained with oxygen 33%: Nitrous oxide 66% with sevoflurane 1-2%. Any changes in pulse rate, blood pressure, airway pressures at the time of placement of airway device recorded.

Results
There were no statistical difference in patients of age, sex, height, weight, BMI, ASA status or duration of surgery. (p-value >0.05).

|                          | I        | E        |
|--------------------------|----------|----------|
| AGE(YRS)                 | 45.30    | 46.85    |
| HEIGHT IN CM             | 159.00   | 158.55   |
| WEIGHT(KG)               | 62.28    | 61.60    |
| B.M.I.                   | 24.58    | 24.35    |
| DURATION OF SURGERY IN MINS | 81.20   | 83.13    |
| NO. OF ATTEMPTS OF INSERTION | 1.13    | 1.10     |
| DURATION OF INSERTION IN SECONDS | 14.98  | 19.23    |

The number of attempt taken to place the i-gel or endotracheal tube was not significant but the duration of time to place the i-gel v/s ETT was quite less.....14.98 v/s 19.23 sec (p-value <= 0.05). There was a significant increase in the heart rate and blood pressure at the time of endotracheal intubation in group E patients from a baseline of 74.10 to 82.30 compare to I gel group varies from 74.10 to 75.15 maximum (p-value <0.05).
HEART RATE | I | E | Systolic blood pressure | I | E | Diastolic blood pressure | I | E
---|---|---|---|---|---|---|---|---
BASELINE | 74.10 | 74.08 | SBP0 | 123.33 | 124.10 | DBP0 | 72.53 | 73.98
T1 | 74.45 | 80.20 | SBP1 | 123.08 | 131.13 | DBP1 | 73.25 | 83.70
T2 | 74.85 | 80.88 | SBP2 | 123.20 | 131.00 | DBP2 | 73.88 | 84.18
T3 | 75.15 | 74.33 | SBP3 | 123.73 | 123.10 | DBP3 | 73.85 | 74.93
T4 | 82.05 | 80.43 | SBP4 | 128.13 | 129.75 | DBP4 | 80.90 | 80.30
T5 | 82.58 | 82.30 | SBP5 | 129.40 | 129.65 | DBP5 | 81.38 | 80.68
T6 | 82.78 | 81.98 | SBP6 | 130.35 | 129.85 | DBP6 | 81.73 | 80.80
T7 | 82.50 | 81.88 | SBP7 | 130.58 | 129.95 | DBP7 | 81.88 | 80.83
T8 | 82.63 | 81.63 | SBP8 | 131.08 | 129.63 | DBP8 | 82.15 | 80.63
T9 | 82.18 | 81.53 | SBP9 | 130.63 | 129.40 | DBP9 | 82.20 | 80.18
T10 | 82.10 | 81.45 | SBP10 | 129.75 | 129.10 | DBP10 | 81.98 | 80.78
T11 | 81.88 | 81.60 | SBP11 | 129.00 | 129.03 | DBP11 | 81.78 | 80.65
T12 | 81.53 | 81.50 | SBP12 | 128.60 | 128.83 | DBP12 | 80.98 | 80.25
T13 | 81.25 | 81.65 | SBP13 | 127.18 | 129.38 | DBP13 | 80.15 | 80.60
T14 | 80.75 | 81.83 | SBP14 | 126.55 | 128.68 | DBP14 | 78.95 | 80.58
T15 | 80.58 | 81.63 | SBP15 | 125.90 | 127.63 | DBP15 | 78.30 | 80.53
T16 | 80.03 | 82.03 | SBP16 | 124.95 | 126.15 | DBP16 | 77.68 | 79.70
T17 | 80.05 | 86.48 | SBP17 | 124.35 | 123.18 | DBP17 | 77.40 | 74.88
T18 | 79.88 | 88.05 | SBP18 | 123.55 | 125.30 | DBP18 | 76.98 | 75.18
T19 | 79.95 | 88.43 | SBP19 | 123.40 | 129.45 | DBP19 | 77.20 | 80.75
T20 | 79.95 | 88.08 | SBP20 | 123.05 | 129.58 | DBP20 | 77.08 | 80.55
T21 | 79.55 | 79.90 | SBP21 | 123.03 | 123.18 | DBP21 | 77.15 | 74.53

The mean blood pressure was 123.33 mmHg in group I and 124.10 mmHg in group E. A significant rise in Systolic Blood Pressure is seen at 1 and 5 minutes in group E and a similar trend seen in extubation. No changes in pressures recorded during pneumoperitoneum. Similar trends were seen in diastolic blood pressures where a significant increase in diastolic blood pressure seen in the group E (p < 0.05). No significant differences recorded in the mean airway pressure in both the groups before, during and after the pneumoperitoneum (p > 0.05).
The average airway pressures recorded are 15+-4.4 and 14+-4.32. Although the leak volume was more in the group I compare to group E, there was no effect on ventilation or oxygenation to any patient of any groups. None of the patient in both the groups had any incidence of fall in saturation or hypercapnia at any point of time.

| End Tidal co2 | I   | E   | SATURATION | I   | E   |
|---------------|-----|-----|------------|-----|-----|
| ET1           | 33.53 | 33.30 | SP0       | 98.95 | 98.95 |
| ET2           | 33.35 | 33.45 | SP1       | 99.38 | 99.23 |
| ET3           | 33.30 | 33.73 | SP2       | 99.05 | 99.33 |
| ET4           | 40.93 | 40.50 | SP3       | 99.30 | 99.55 |
| ET5           | 40.70 | 40.83 | SP4       | 99.10 | 99.30 |
| ET6           | 40.60 | 40.65 | SP5       | 99.10 | 99.23 |
| ET7           | 40.75 | 40.65 | SP6       | 99.48 | 99.58 |
| ET8           | 40.78 | 40.53 | SP7       | 99.43 | 99.28 |
| ET9           | 40.68 | 40.65 | SP8       | 99.35 | 99.40 |
| ET10          | 40.68 | 40.73 | SP9       | 99.25 | 99.48 |
| ET11          | 40.75 | 40.58 | SP10      | 99.43 | 99.68 |
| ET12          | 40.58 | 40.45 | SP11      | 99.38 | 99.38 |
| ET13          | 40.68 | 40.53 | SP12      | 99.33 | 99.55 |
| ET14          | 40.68 | 40.45 | SP13      | 99.35 | 99.58 |
| ET15          | 39.43 | 40.70 | SP14      | 99.35 | 99.53 |
| ET16          | 33.33 | 33.83 | SP15      | 99.25 | 99.45 |
| ET17          | 33.30 | 34.05 | SP16      | 99.35 | 99.45 |
| ET18          | 33.45 | 34.18 | SP17      | 99.40 | 99.65 |

**Discussion**

Laparoscopic cholecystectomy is one of the most common surgery done in day to day practice. Till date endotracheal intubation is one of the common technique used to secure the airway during this surgery, but use of supraglottic airway device; an i-gel is also used safely to ventilate and oxygenate both the lungs. Apart from better hemodynamic stability and lesser chances of throat discomfort post-operatively, we did a prospective, randomized, double blind study to compare the insertion qualities, hemodynamic changes, ventilatory parameters and post operative complications of i-gel and endotracheal intubation in patients posted for laparoscopic cholecystectomies.

The data in our study was comparable regarding the age, sex, height, weight, and BMI in the two groups. The base line parameters like heart rate, systolic and diastolic pressures were also comparable in the two groups. The size of the i-gel according to the weight criteria of manufacturer’s recommendations: size 3 for 30-60 kg and size 4 for 50-90 kg. We inserted 13 size 3 i-gel and 27 size 4 i-gels. The i-gel was placed in first attempt in 35 out of 40 patients (i.e in 87.5%) and 5 out 40 patients required second attempt with little airway manipulations like jaw lifting. The endotracheal tube was placed in almost 90 percent of the patients in first attempt. The endotracheal tube were placed in first attempt in 36 out of 40 patients and only 4 patients required a second attempt at intubation using
stylet. Regarding the no. of attempts of insertion of the device, the p value is 0.723. There is no significant difference in the attempts of insertion in the two groups. The mean time of insertion of i-gel was significantly less as compared to the endo tracheal tube group. In the i-gel group it was 14.98 secs +/- 1.00 as compared to the group E 19.23 secs+/-.1.25 (p value = 0.005). ANJAN DAS et al reported in their study on ambulatory anaesthesia in 2014 where he compared i-gel LMA to Proseal LMA concluded that i-gel was inserted in shorter time than PLMA (14.9 vs 20.00 secs). Hemodynamics were less altered in i-gel than PLMA and the results were statistically significant (p<0.05)\(^{10}\). OSMAN et al, comparing the ProSeal and i-gel laryngeal mask airways in anaesthetized adult patients under controlled ventilation concluded that i-gel is a good alternative to P-LMA since it can be inserted faster and easier as well allows easier insertion of the nasogastric catheter. The mean insertion time in the i-gel [8 +/- 3]group was significantly lower than the PLMA group [13/-/5]. The insertion success rate was higher in the i-gel group [100 %, first attempt] than in the P-LMA group [82.5%, first attempt]. The gastric tube placement success rate was higher in the i-gel group [92.5%, first attempt] than in the P-LMA group [72.5%, first attempt]. The airway leakage pressures were similar\(^{19}\). All the above findings also supports our results. We also observed that i-gel can be more easily inserted and in lesser time 14.98 Sec. Vs 19.23 Sec. Laryngoscopic guided intubation evokes rise in hemodynamic response. We observed a significant rise in heart rate, systolic blood pressure and diastolic blood pressure just after 1min, 5min, post endotracheal intubation when compared to i-gel as a reflection of an increase in sympathoadrenal activity due to oropharyngeal and laryngotracheal stimulation. JIGISHA et al, in 2015 also supporting our study as well as the results, by using i-gel as an alternative to endotracheal tube in adult laparoscopic surgeries. There was significant rise in pulse rate and mean blood pressure during tracheal intubation compared to i-gel. There was no significant difference in the PR (P = 0.18, df-58, CI-95%) and MBP (P = 0.292, df-58, CI-95%) before insertion of airway device between the two group. Following insertion of airway device there was significant rise in PR (just after intubation [P = 0.0013, df-58, CI-95%], 3 min after intubation [P = 0.011, df-58, CI-95%]) and MBP (just after intubation [P = 0.0002, df-58, CI-95%], 3 min after intubation [P = 0.0001, df-58, CI-95%], 5 min after intubation [P = 0.014, df-58, CI-95%]) in Group-B patients when compared to Group-A patients. However after 5 min of intubation till the removal of airway device the changes in PR and MBP were comparable in both groups. SpO2 2 and EtCO2 between the two groups were comparable at all times\(^{10}\). In our study, the base line heart rates at T0 were comparable in both the groups. Immediately after intubation the mean heart rate at T1 was 74+/-.746 as compared to the endotracheal tube group 80+/-.7.39 with a p value of 0.001. there is no significant difference in the base line heart rates in the two groups p=0.938. The similar trends were observed with systolic and diastolic pressures after intubation p value =0.000. Although the baseline systolic and diastolic pressures were comparable in two groups p=0.357 and p=0.481 respectively. Therefore, a significant difference in hemodynamic parameters is observed at the time of intubation with endotracheal tube as compared to i-gel group and our results were comparable to the above mentioned studies. GABBOTT et al concluded that i-gel provides a good airway sealing pressure which improved over time and may be due to the thermoplastic properties of gel cuff which forms an effective seal around the larynx after warming to body temperature. Various studies have been conducted comparing the seal pressure of i-gel with other LMA’s, which conclude that an i-gel has an airway sealing pressure almost similar to the LMA Proseal and more than the Classic LMA and LMA unique, hence can be used for positive pressure ventilation without the risk of aspiration\(^{11}\). In our study we observed that i-gel
formed an effective seal around the glottis allowing adequate oxygenation and controlled ventilation as good as ETT. EtCO 2 were comparable in both groups. During carboxyperitoneum minute ventilation was increased mainly by increasing the respiratory rate rather than tidal volume. This was done to eliminate raised carbon dioxide load and prevent systemic acidosis. A study by GURUDAS et al, showed that time required for insertion of i-gel was lesser [21.98+/−5.42sec] as compared to ProSeal [30.60+/−8.51 sec] P=0.001. The mean airway leak pressures were comparable [P=0.25]. it was 23.58 and 21.83 cm H2O in group i-gel and group proseal respectively. studies on supraglottic airway devices suggest that mean peak airway pressure of more than 20 cm H2O increases the risk of leakage with resultant inefficient ventilation and increased risk of aspiration. Uppal et showed that the i-gel had no significant difference in gas leak compared with the tracheal tubes when ventilating at moderate pressures up to 15-20 cm H2O, but did not study pressures higher than 25 cm H2O. Our study was comparable to the above mentioned studies. The airway pressure were comparable in the two groups. we did not observe rise in airway pressures in the i-gel group with pneumoperitoneum. The ventilation and oxygenation were adequate in the i-gel group and comparable to that of endotracheal group. Tidal volume was kept in the range of 6 to 8 ml per kg and intra-abdominal pressure during pneumoperitoneum was between 10 -15 mm Hg. In our study we observed that patients in i-gel group were adequately ventilated with moderate tidal volumes of 6-8 ml per kg and the leak volume was also within acceptable limits. Devices with an inflatable mask have the potential to cause tissue distortion, venous compression, and nerve injury, which explains the increased incidence of associated post operative morbidity. Trauma on insertion due to multiple insertions ,and pressure exerted by cuff against the pharyngeal mucosa ,cuff volumes, all have been incriminated for post operative complications. Various studies have reported similar findings where in the incidence of sore throat is minimal with i-gel in comparison with other supraglottic airway devices. The lower incidence of sore throat in our study can be attributable to the soft seal non inflatable mask of i-gel.

Conclusion
To conclude I-gel is a better, safe and reliable option to endotracheal intubation in patients for laparoscopic cholecystectomy in terms of hemodynamic stability, airway pressures, leak volume and post-operative discomfort.

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