



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

Authors

**Dr Bhawna Ahluwalia¹, Dr Manjit Singh Kanwar², Dr Ankita Chandel^{3*},
Dr Nisha Sharma⁴, Dr Naresh Anand⁵**

¹Senior Resident, Dr Radhakrishnan Government Medical College, Hamirpur

^{2,3}Assistant Professor, Dr Radhakrishnan Government Medical College, Hamirpur

⁴Senior Resident, Dr Radhakrishnan Government Medical College, Hamirpur

⁵Consultant Anaesthesia, SPS Hospitals, Ludhiana

*Corresponding Author

Dr Ankita Chandel

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-I & 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 Sysolic and diastolic Blood Pressure is seen 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 general anaesthesia 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 fourty 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.

	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

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).

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 124.10mmhg in group E. A significant rise in Systolic Blood Pressure is seen at at 1 and 5 minutes in group E and a similar trends 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).

Airway Pressures	I	E	Leak Volume	I	E
P1	9.85	9.85	LV1	15.55	13.13
P2	10.83	10.83	LV2	15.25	12.25
P3	11.18	10.30	LV3	14.95	12.28
P4	11.83	10.23	LV4	15.23	12.58
P5	18.90	18.58	LV5	15.23	11.73
P6	19.23	18.78	LV6	15.40	12.08
P7	18.48	18.65	LV7	15.43	12.98
P8	18.73	19.13	LV8	15.10	12.38
P9	18.50	18.83	LV9	14.98	12.18
P10	19.03	19.13	LV10	15.25	12.60
P11	19.38	19.10	LV11	15.38	12.28
P12	19.85	19.43	LV12	15.10	11.88
P13	18.95	18.75	LV13	15.05	12.18
P14	19.15	18.78	LV14	15.43	12.95
P15	19.15	18.30	LV15	15.23	12.50
P16	10.33	10.05	LV16	15.25	11.68
P17	10.35	9.78	LV17	15.13	12.63
P18	10.20	9.73	LV18	15.15	12.58

The average airway pressures recorded are 15+-4.4 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
			SP18	99.43	99.68
			SP19	99.40	99.63
			SP20	99.33	99.58
			SP21	99.28	99.25

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.^(6,7,8)

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 endotracheal 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 ($p < 0.05$)⁽¹⁶⁾. 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⁽⁹⁾. 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. V/s 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 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 +/- 7.46 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. EtCO₂ were comparable in both groups. During carboperitoneum 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 21.83cm 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.⁽¹²⁾ Uppal et al 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.⁽¹¹⁾ 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.^(13,14,15) 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.^(10,11,16)

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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