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A comparative study between I-gel and endotracheal tube in elective laparoscopic cholecystectomy surgeries under general anesthesia

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ABSTRACT

Background: With increase in incidence of gall bladder stone the laparoscopic cholecystectomy preferred in various hospitals. Laryngoscopic stimulation of oropharyngeal and laryngeal structures leads to hemodynamic stress response. I-gel is a second generation supraglottic airway device with noninflatable cuff, having several advantages such as minimal hemodynamic changes during insertion and easy to insert. **Aims and Objectives:** The aim of this study was to compare I-gel and endotracheal tube regarding hemodynamic stability, adequacy of ventilation, ease of insertion through number of attempts, and time for insertion and associated complications in patients undergoing laparoscopic cholecystectomy. **Materials and Methods:** Total 60 patients of either sex, 25–55 years age of ASA Grades I and II were randomly allocated into two groups of 30 patients each; Group A (endotracheal tube) and Group B (I-gel). Ease of insertion in terms of number of attempts and time for insertion, hemodynamic variation and their complications were recorded. **Results:** Significantly less time was required for insertion of I-gel as compared to endotracheal tube ($P=0.04$), while number of attempts required for insertion were comparable, highly significant difference in heart rate, systolic blood pressure, mean arterial pressure just after insertion and at extubation of endotracheal tube than I-gel group ($P<0.01$), peak airway pressure at insufflation with endotracheal tube was highly significant ($P<0.01$), and SPO_2 and $ETCO_2$ were comparable. The complications were statistically insignificant among the study groups. **Conclusion:** Comparison to endotracheal tube, I-gel required less time and less number of attempts for insertion and causes fewer hemodynamic alterations. In addition, peak airway pressure was also significantly more in endotracheal tube just before and at pneumoperitoneum.

Key words: Endotracheal tube; I-gel; Supraglottic airway devices; Laparoscopic cholecystectomy

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INTRODUCTION

Conventional open surgeries are nowadays being replaced by minimal invasive laparoscopic surgeries. At the same time, airway management from the patient being intubated with endotracheal tube to more lesser invasive supraglottic airway devices like I-gel.[1] Laparoscopic surgery is preferred because of several advantages such as less bleeding, small incision, minimal surgical scar, early ambulation, and less hospital stay. As there is insufflation of carbon dioxide in the peritoneal cavity, it results in raised abdominal pressure, increased $EtCO_2$, hemodynamic changes, cardiovascular changes, or regurgitation.[2,3] Trendelenburg position is the most commonly used position for laparoscopic cholecystectomy.[4] Even though endotracheal intubation has been used as a gold standard method, recently LMAs are used to secure airway with fewer complications and lesser hemodynamic changes as a substitute to

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endotracheal intubation.[5] Newer supraglottic second generation airway devices such as proseal LMA and I-gel have replaced the classical laryngeal mask airway as they form more effective seal and has a port that facilitates the suction of gastric contents and prevent gastric insufflation and regurgitation. The widened flat stem of I-gel has a rigid bite block that prevents the occlusion of the airway during recovery. Still the supraglottic airway devices such as classical LMA and LMA supreme have an increased risk of insufficient ventilation and pulmonary aspiration as compared to endotracheal intubation.[4] Gastric tube provide protection against regurgitation and prevents gastric insufflation, better oxygenation during emergence, and decreased post-operative sore throat and voice alteration.[6,7]

I-gel is a single use second generation supraglottic airway device made of medical grade thermoplastic elastomer. It has a non-inflatable cuff to reduce the complications associated with compression, trauma and high pressure and it provides a tight seal sufficient for maintain spontaneous as well as intermittent positive pressure ventilation.[8,9]

Aims and objectives

To compare I-gel and endotracheal tube regarding hemodynamic stability, adequacy of ventilation and to assess the ease of insertion through number of attempts and time for insertion of I-gel and endotracheal tube in patients undergoing laparoscopic cholecystectomy, complication associated with I-gel and endotracheal tube were also observed.

MATERIALS AND METHODS

This randomized prospective study was conducted on 60 patients admitted to JA group of hospital of ASA Grades I and II, aged 25–55 years, undergoing laparoscopic cholecystectomy surgeries, after the approval from ethic committee of the institute and informed and written consent from the patients.

Sample size

$$n = \frac{\left(s_1^2 + s_2^2\right)\left(Z_{\alpha/2} + Z_{1-\beta}\right)^2}{\left(\mu_1 - \mu_2\right)^2}$$

After induction mean arterial pressure (MAP) for the I-gel was 97.32±6.9 and MAP after induction in ET tube[7] was 105.55±7.09.

s_1=6.99, s_2=7.09, μ_1=97.32, μ_2=105.55, at 5% level of significant for two tailed.

$Z_{\alpha/2}$=1.96, $Z_{1-\beta}$=1.64, At 95% power of test.

$$n = \frac{\left(6.99^2 + 7.09^2\right)\left(1.96 + 1.64\right)^2}{\left(97.32 - 105.55\right)^2}$$

$$= 19.02 \cong$$

Minimum sample size for each procedure I-gel and ET tube was 20–20.

The sample size was increased to 30 in each group, so total sample size for our study was 60.

Inclusion criteria

Patient aged 25–55 years, ASA Grades I and II giving consent for participate in study with Mallampati Grades I and II were included in the study.

Exclusion criteria

Patients having some pathology of neck or upper respiratory tract, increase risk of aspiration (full stomach, GERD), difficult airway, emergency surgeries, chronic diseases (hypertension, diabetes mellitus, bronchitis, and bronchial asthma) and with negative consent were excluded from the study.

Patients were randomly allocated into two groups using flipping a coin method of randomization.

- Group A (n=30) where endotracheal tube of appropriate size was used to secure airway after induction of general anesthesia
- Group B (n=30) where I-gel of appropriate size was used to secure airway after induction of general anesthesia.

After routine pre anesthetic assessment patients were taken in operation theatre. Well informed and written consent was taken and intravenous access secured. All baseline parameters were attached and recorded (pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), MAP, and SPO_2). All patients were uniformly premedicated with Inj. Ondansetron (0.1 mg/kg) and Inj. Glycopyrrolate (0.2 mg) intravenously and Inj. Pentazocine (0.3–0.6 mg/kg), pre-oxygenated with 100% oxygen for 3 min.

Group A was induced with Inj. Propofol (2–2.5 mg/kg) I/V and Inj. Succinylcholine (1–1.5 mg/kg) then trachea was intubated with appropriate size of cuffed endotracheal tube and bilateral air entry checked and cuff inflated.

Group B was induced with Inj. Propofol 2–2.5 mg/kg I/V and Inj. Succinylcholine (1–1.5 mg/kg) then I-Gel of appropriate size was inserted. Just after insertion of device (heart rate, SBP, DBP, MAP, $ETCO_2$, airway pressure, and SPO_2) was recorded.

Correct placement of devices was confirmed by chest wall movement, bilateral chest auscultation and presence of square wave of capnogram.

Anesthesia was maintained with N_2O: O_2 (67:33) with isoflurane and relaxation was maintained with Inj. Atracurium 0.1 mg/kg. Intraoperative monitoring and recording of pulse rate, blood pressure (SBP, DBP, MBP), SpO_2, airway pressure, $EtCO_2$, was done at the time of induction, and at the interval of 1 min, 3 min, 5 min, at insufflation of CO_2 in peritoneum, 10 min after insufflation (P-10) and at extubation.

Ease of insertion was also assessed in terms of; (1) number of attempts and (2) time for insertion of respective devices.

Residual effects were reversed by Inj. Neostigmine 2.5 mg I/V and Inj. Glycopyrrolate 0.5 mg IV once patient started breathing spontaneously. Airway devices were removed on return of airway reflexes and muscle tone.

Statistical analysis

Evaluation of study data in electronic form required performing additional statistical analyses. Data were composed in suitable spreadsheet, that is, EXCEL and SPSS. After compilation of data, it was analyzed statistically by SPSS software version 22.0. Statistical tests used were student t-test (paired and unpaired) and Chi-square test. Significance level will be 95% confidence level ($P<0.05$). Data were described as a frequency (percentage) distribution as well as in mean±SD. ($P<0.05$) was considered significant and $P<0.001$ was considered highly significant.

RESULTS

In our study, 60 patients scheduled for elective laparoscopic cholecystectomy surgeries under general anesthesia were included in the study. Patients randomly selected and divided into two groups (30 in each group):

Demographic association as shown in Table 1, found to be statistically not significant ($p>0.05$) which shows the demographically both groups were comparable..

Ease of insertion

Ease of insertion was assessed in terms of number of attempts and time for insertion.

In this study, it was found that I-gel require less number of attempts as compare to endotracheal tube but that was statistically insignificant ($P>0.05$).

As shown in Table 2, association found to be statistically significant ($p<0.05$) showing faster time of insertion in group B compare to Group A.

The hemodynamic variables was calculated at Baseline, Induction, 1 min, 3 min, 5 min, at insufflation, P-10 min, and at extubation in both the groups.

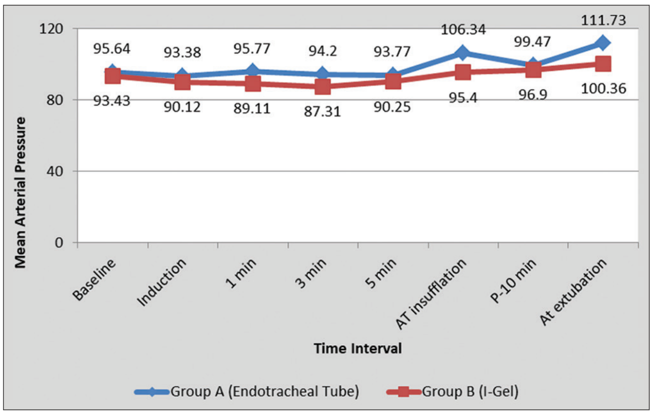

Figure 1: Comparison of mean arterial pressure between the groups

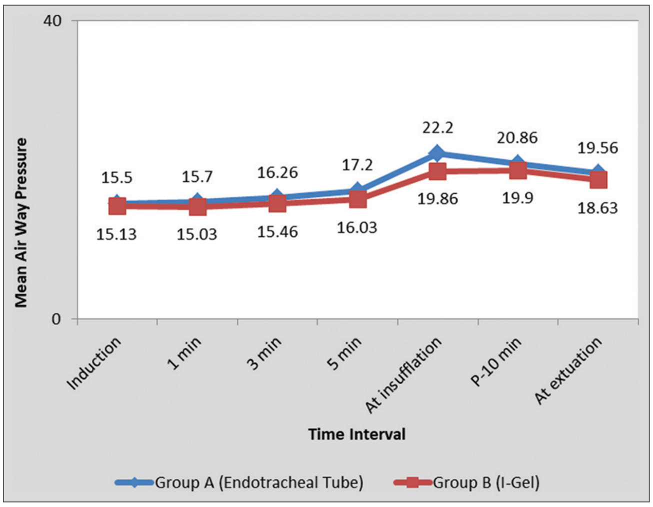

Figure 2: Comparison of mean air way pressure between the groups

Table 1: Demographic variables in both the groups

Demographic parameter	Group A (n=30)	Group B (n=30)	P-value
Age (years)	44.47±8.56	40.40±7.40	0.054
Weight (kg)	65.37±5.71	63.77±6.67	0.323
Height (cm)	160.53±5.92	158.80±5.14	0.231
Gender (%)			
Male	8 (26.7)	3 (10)	0.095
Female	22 (73.3)	27 (90)	

Table 2: Time of insertion (in seconds)

Group	n	Mean±SD	t-value	P-value
Group A (endotracheal tube)	30	13.33±2.106	3.041, df=58	0.004*
Group B (I-Gel)	30	11.70±2.054		

*=significant

Table 3: Comparison of mean heart rate between the groups

Time interval	n	Group A (endotracheal tube)	Group B (I-Gel)	t-value	P-value
Baseline	30	81.06±8.73	81.16±8.52	−0.045, df=58	0.964
Induction	30	84.36±8.64	80.46±7.48	1.869, df=58	0.067
1 min	30	100.40±8.20	80.10±7.42	10.050, df=58	0.000**
3 min	30	87.73±7.73	81.66±6.91	3.202, df=58	0.002*
5 min	30	86.86±9.20	82.56±8.32	1.898, df=58	0.063
At insufflation	30	94.56±8.74	84.06±7.79	4.911, df=58	0.000**
P-10 min	30	85.86±10.54	84.73±7.94	0.470, df=58	0.640
At extubation	30	102.83±9.06	86.10±7.30	7.872, df=58	0.000**

*=significant, **=highly significant

Table 4: Comparison of mean systolic blood pressure between the groups

Time interval	n	Group A (endotracheal tube)	Group B (I-Gel)	t-value	P-value
Baseline	30	118.20±12.50	117.23±8.34	0.352, df=58	0.726
Induction	30	115.83±8.82	114.03±10.06	0.737, df=58	0.464
1 min	30	122.93±8.69	112.46±8.80	4.631, df=58	0.000**
3 min	30	122.86±9.09	109.33±7.20	6.387, df=58	0.000**
5 min	30	120.33±8.73	118.43±10.41	0.766, df=58	0.447
At insufflation	30	139.50±10.84	115.66±14.73	7.135, df=58	0.000**
P-10 min	30	124.96±8.50	126.23±7.46	−0.613, df=58	0.542
At extubation	30	150.20±8.32	132.36±4.46	10.336, df=58	0.000**

**=highly significant

Table 5: Comparison of mean diastolic blood pressure between the groups

Time Interval	n	Group A (endotracheal tube)	Group B (I-Gel)	t-value	P-value
Baseline	30	84.36±7.81	81.53±9.24	1.282, df=58	0.205
Induction	30	82.16±7.90	78.16±9.42	1.781, df=58	0.080
1 min	30	82.20±10.03	77.43±11.12	1.743, df=58	0.087
3 min	30	79.86±8.29	76.30±6.82	1.818, df=58	0.074
5 min	30	79.53±8.91	76.16±7.01	2.114, df=58	0.109
At insufflation	30	89.76±8.97	85.26±7.09	2.155, df=58	0.035*
P-10 min	30	86.73±9.54	82.86±7.04	1.812, df=58	0.075
At extubation	30	92.50±7.47	84.36±7.08	4.324, df=58	0.000**

*=significant, **=highly significant

Table 3 shows that Baseline, Induction, 5 min and P-10 min values were comparable, rest all values were highly significant showing that the rise of mean heart rate was more in Endotracheal Tube as compared to I-Gel ($P<0.05$).

With reference to Table 4, Baseline, Induction, 5 min and P-10 min values were comparable, rest all values were highly significant showing that the rise of SBP was more in Endotracheal Tube as compared to I-Gel ($P<0.05$).

With reference to Table 5 Baseline, Induction, 1 min, 3 min, 5 min and P-10 min values were comparable, rest all values were highly significant showing that the rise of DBP was more in endotracheal tube as compared to I-Gel ($P<0.05$).

As shown in Figure 1, Baseline, induction and P-10 values were comparable, 5 min value was significant ($P<0.05$) rest all values were highly significant ($P<0.001$) showing that the rise of MAP was more in endotracheal tube as compared to I-Gel.

After analysis Figure 2, it was found that there was significant increase in mean airway pressure at 5 min ($P=0.035$) after intubation and highly significant difference at insufflation ($P=0.000$) from baseline value in endotracheal tube group than I-gel groups.

Complications

In our study, post-operative complications were comparable in both groups, Group A had 10% incidence of nausea and vomiting and 16.7% incidence of sore throat where as I-gel had only 3.3% incidence of nausea, vomiting, and sore throat which was statistically insignificant ($P>0.05$).

DISCUSSION

Minimally invasive laparoscopic surgeries are now replacing traditional open surgeries.[1] Patients undergoing laparoscopic cholecystectomy had lower levels of operation-related indices than those undergoing open cholecystectomy or small-incision cholecystectomy, indicating that laparoscopic cholecystectomy effectively reduced operative time, intraoperative bleeding volume, smaller surgical scar, earlier ambulation, and a shorter hospital stay.[2]

Although endotracheal intubation was once considered the gold standard method, classical LMA are now used as a substitute for endotracheal intubation because they have fewer complications and cause less hemodynamic changes.[3] As time has passed, newer supraglottic second generation airway devices such as proseal LMA and I-gel have replaced the traditional laryngeal mask airway because they form a more effective seal and have a drainage port that facilitates gastric tube passage. It protects against regurgitation and prevents gastric insufflation, improves oxygenation during emergence, and reduces post-operative sore throat and voice changes.[4]

In the present study, we aimed to compare I-gel and endotracheal tube regarding hemodynamic stability, adequacy of ventilation, ease of insertion through number of attempts and time for insertion and also observe associated complications in patients undergoing laparoscopic cholecystectomy under general anesthesia.

In the present study, the demographic data were comparable ($P>0.05$) with respect to age (in year) with the mean+SD 44.47±8.56 in Group A and 40.40±7.40 in Group B. Weight (in Kg) mean±SD 65.37±5.71 in Group A and 63.77±6.67 in Group B. Height (in cm) with mean±SD in Group A (Endotracheal Tube) was 160.53±5.92 cm and in Group B (I-Gel) it was 158.80±5.14 cm, respectively.

There were 8 (26.7%) males and 22 (73.3%) females in Group A and in Group B there were 3 (10.0%) males and 27 (90.0%) females. This association was also found to be statistically not significant ($P>0.05$), similar finding was also found in previous study.[7]

In this study, on comparing the ease of insertion in terms of number of attempts and time for insertion, it was found that the mean time of insertion in Group A (Endotracheal Tube) was 13.33±2.106 s and in Group B (I-Gel) it was 11.70±2.054 s. This association was found to be statistically significant ($P<0.05$) which means that there was significantly less time required for insertion of I-gel as compared to endotracheal tube because I-gel does not required laryngoscopy for insertion so less time was required. On the other hands in view of number of attempts, I-gel was successfully inserted in first attempt in 90% of the patients while 73.3% patients of endotracheal tube group were intubated in 1st attempt and rest of all patients were intubated in the 2nd attempt but this association was found to be statistically insignificant ($P>0.05$), similar finding was also found in the previous study.[3,10]

In the present study, various hemodynamic parameters were analyzed such as heart rate, SBP, DBP, MAP, $EtCO_2$, airway pressure, and SPO_2 and were noted down at base line, induction, 1 min, 3 min, 5 min, at insufflation, P-10 min, and at extubation for patients of both Groups A and B.

On comparing the mean heart rate and SBP, it was observed that there was statistically highly significant increase in heart rate and SBP at 1 min, 3 min after intubation, at insufflations, and at extubation in endotracheal group ($P<0.01$) and there was highly significant increase in MAP at 1 min, 3 min, 5 min after intubation, at insufflation, and at extubation ($P<0.05$) because endotracheal intubation requires laryngoscopy which evokes further rise in hemodynamic response and there were also significant increase in mean DBP at insufflation and at extubation ($P<0.05$). Similar finding were also found with the previous study.[9,10]

In the present study, after analysis it was found that there were no significant differences in mean $ETCO_2$ and SPO_2 from baseline value between the endotracheal and I-gel groups ($P>0.05$) because I-gel is found to be equally effective as endotracheal tube to secure airway, Similar finding was observed with the previous study.[11,12]

Significant increase in mean airway pressure at 5 min ($P=0.035$) after intubation and highly significant difference at insufflation ($P=0.000$) from baseline value in endotracheal tube group than I-gel groups. Similar results were observed by the previous studies.[13,14]

The post-operative complications were comparable in both groups, Group A had 10% incidence of nausea and vomiting and 16.7% incidence of sore throat where as I-gel had only 3.3% incidence of nausea, vomiting, and sore throat which was statistically insignificant ($P>0.05$).

Limitations of the study

As in this study, only patients with ASA Grades I and II and mallampatti Grades I and II were included in the study. There was also no comparison of other supraglottic airway devices such as proseal LMA.

CONCLUSION

This study concludes that I-gel required less number of attempts and less time for insertion in comparison to endotracheal tube with the use of muscle relaxant in both group, the hemodynamic variability significantly more in endotracheal group few minutes after induction, at pneumoperitoneum and just after extubation. Peak airway pressure was also significantly more in endotracheal group just before and at pneumoperitoneum. I-gel provide an effective positive pressure ventilation in comparison to endotracheal tube with no significant changes in $ETCO_2$ and SPO_2.The complication such as nausea, vomiting, and sore throat were also more with endotracheal tube than I-gel but statistically insignificant. I-gel is therefore a perfect substitute for an endotracheal tube in elective laparoscopic cholecystectomy procedures performed under general anesthesia.

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Authors' Contributions:
KA- Literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation, and submission of article; **SG-** Concept, design, clinical protocol, manuscript preparation, editing, manuscript revision, and supervision; **AG-** Design of study, statistical analysis, and interpretation; **SPT-** Concept, coordination and preparation of manuscript; **PG-** Proofreading and revision of manuscript.

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