

Assessment of I-Gel as an Alternative to Endotracheal Tube in Adult Laparoscopic Surgeries

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Abstract: Laparoscopic surgeries are fast replacing the open surgeries for a number of surgical procedures. I-gel promises to overcome the limitations of endotracheal tube airway management. This study was done to compare the endotracheal tube and I-gel in view of insertion time, intraoperative hemodynamic parameters, difference in peak airway pressure and complications like cough/sore throat, nausea/vomiting and dysphonia. It is observed that I-gel can be a possible alternative to endotracheal tube.

Material and Methods: A prospective double blind randomized controlled trial was conducted in a tertiary care hospital in Lucknow over a period of one year. ASA status I or II, aged 16 to 60 years, undergoing laparoscopic surgeries under general anesthesia were enrolled. The anticipated duration of surgery was up to two hours. In Group-I (ETT) patient's airway was secured with laryngoscopy guided endotracheal intubation whereas in Group II (I-gel) appropriately sized I-gel was inserted. Intraoperative and postoperative events were compared. All the results were analyzed using students t- test, paired t- test and chi-square test.

Results: Range of time of insertion of airway device in Group I was 13.6-16.8 seconds while that in Group II was 9.0-12.2 seconds. Difference in mean time of insertion of airway device of patients of Group I (ETT) (14.11 ± 0.63 sec) and Group II (I-gel) (9.88 ± 0.79 sec) was found to be statistically significant. At all the periods of observation heart rate, systolic, diastolic mean blood pressures of patients of above two groups were found to be comparable. Differences in peak airway pressure of patients of above two groups were not found to be significant statistically at any of the above periods of observation.

Most common complications as nausea/vomiting ($n=21$; 35.0%), cough and dysphonia were found in higher proportion in patients of Group I as compared to Group II, but these differences were not found to be significant statistically.

Conclusion: I-gel is found to be equally effective as endotracheal tube to secure airway and could be proposed as an alternative to ETT with lesser intraoperative and postoperative complications

Keyword: Laparoscopic surgery, endotracheal tube, I-gel, intraoperative and postoperative events.

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I. Introduction

The cuffed endotracheal tube is considered an ideal modality to provide a safe glottic seal in laparoscopic surgeries. I-gel promises to overcome the limitations of endotracheal tube airway management. I-gel is made up of a thermoplastic elastomer that is soft, gel-like, transparent, and structured to be fit to the perilaryngeal and hypopharyngeal structure, so that it does not require an inflatable cuffⁱ. There is an independent gastric drain tube that allows the insertion of the gastric tube for the aspiration of air and the residual gastric fluid. A widened flat stem of I-gel has a rigid bite-block that prevents the occlusion of the airway during recoveryⁱⁱ. Studies performed on mannequin and patients have shown that the insertion of I-gel was significantly easier when compared with insertion of other supraglottic airway devices.^{iii,iv} Owing to ease of insertion and a better hemodynamic stability, I-gel is considered as an effective alternative to cuffed ETT in patients with high risk and an anticipated difficult airway.^{v,vi} A recent case series has indicated that the routine use of the endotracheal tube did not reduce mortality due to aspiration^{vii,iii}. In view of these limitations of endotracheal tube, several supraglottic devices like ProSeal laryngeal mask airway (PLMA) and I-gel for airway management^{ix} promise to overcome the limitations of endotracheal tube airway management. The present study has been planned with an aim to evaluate I-gel as an alternative to endotracheal tube in laparoscopic surgery.

II. Material and Methods

After approval of the hospital ethics committee, 60 adult patients of either sex, of ASA status I or II, aged 16 to 60 years, undergoing laparoscopic surgeries under general anesthesia were studied in this randomized double blinded study protocol. The anticipated duration of surgery was up to two hours.

Exclusion Criteria-

1. Patients having chronic lung disease, pathology of the neck, difficult intubation/ mouth opening <2.5 cm.

2. Patients with cervical spine disease, having increased risk of aspiration *i.e.* those having hiatus hernia, gastro-esophageal reflux disease, full stomach.
3. Morbidly obese patients (BMI >35 kg/m²).
4. Those undergoing emergency surgeries.
5. Non-consenting patients.

In Group-I (ETT) patient's airway was secured with laryngoscopy - guided endotracheal intubation whereas in Group II appropriate sized I-gel was inserted. After fixing the airway device, appropriate sized gastric tube was inserted. For ETT, no. 16 Ryle's tube was used where as for I-gel groups, no. 10 suction catheter was used. The time required for insertion of airway device was recorded. The time for insertion was recorded as time from insertion of the airway device to the first capnograph trace.

The ease of placement (Easy: Inserted in 1st attempt, Difficult: Requires >1 attempt), number of attempts required and failure of gastric tube placement were also noted.

Anesthesia was maintained with O₂, N₂ O, traces of inhalation agents and intermittent doses of injection atracurium. Controlled ventilation was provided with tidal volume of 7-8 ml/kg and respiratory rate set to obtain an end tidal carbon dioxide (EtCO₂) between 35 and 45 mmHg. At the end of surgery, neuromuscular blockade was reversed with glycopyrrolate 8 µg/kg and neostigmine 0.05 mg/kg. Removal of I-gel/extubation of ETT was done after recovery of adequate spontaneous respiration and muscle tone. It was ensured that suction is performed before extubation.

Routine monitoring was done throughout the peri-operative period. Hemodynamic and ventilatory parameters were recorded perioperatively and results were analyzed using students T test, paired T test and chi-square test. Data were expressed as mean ± SD or percentage (p-value < 0.05 was considered statistically significant).

III. Observation and Results

Written informed consent was obtained from sixty adult patients fulfilling the inclusion criteria scheduled to undergo laparoscopic surgery (cholecystectomy (70.0% & 60.0%), hernioplasty (23.3% each) or appendectomy (6.7% & 16.7%). The difference in mean age of patients of Group I (44.53±13.40 years) and Group II (42.53±8.95 years) was not found to be significant statistically. Patients of above two groups were found to be statistically comparable for age and gender and anthropometric parameters. Difference in Physical (ASA Grade) and Nutritional Status (BMI) of patients of above two groups were not found to be statistically significant.

Difference in ease of insertion of airway device among patients of Group I and Group II was not found to be significant statistically ($\chi^2=0.218$; $p=0.640$).

| Group | No. of patients | Min. | Max. | Mean | S.D. |
|----------|-----------------|------|------|-------|------|
| Group I | 30 | 13.6 | 16.8 | 14.11 | 0.63 |
| Group II | 30 | 9.0 | 12.2 | 9.88 | 0.79 |
| Total | 60 | 9.0 | 16.8 | 11.99 | 2.25 |

Table1: Between Group Comparison of Time taken for Insertion of Airway device

Difference in mean time of insertion of airway device Group I (ETT) (14.11±0.63 sec) and Group II (I-gel) (9.88±0.79 sec) was found to be significant statistically. ('t' = 22.866; $p<0.001$)
At baseline, hemodynamic parameters of the patients of above two groups were found to be comparable.

| Time | Group I (n=30) | | | Group II (n=30) | | | Student 't' test | |
|------|----------------|-------|-------|-----------------|-------|-------|------------------|-------|
| | N | Mean | SD | n | Mean | SD | 't' | 'p' |
| BL | 30 | 76.60 | 11.15 | 30 | 81.87 | 9.64 | -1.957 | 0.055 |
| BI | 30 | 76.37 | 10.95 | 30 | 79.40 | 8.42 | -1.202 | 0.234 |
| I | 30 | 81.97 | 11.00 | 30 | 82.83 | 10.69 | -0.309 | 0.758 |
| 1m | 30 | 79.83 | 10.81 | 30 | 80.63 | 11.56 | -0.277 | 0.783 |
| 3m | 30 | 78.53 | 9.24 | 30 | 78.27 | 10.17 | 0.106 | 0.916 |
| 5m | 30 | 76.93 | 8.87 | 30 | 76.67 | 10.06 | 0.109 | 0.914 |
| 10m | 30 | 75.50 | 10.12 | 30 | 75.63 | 8.73 | -0.055 | 0.957 |
| 15m | 30 | 76.50 | 11.05 | 30 | 75.50 | 9.13 | 0.382 | 0.704 |
| 30m | 30 | 75.63 | 10.39 | 30 | 76.57 | 7.87 | -0.392 | 0.696 |
| 45m | 30 | 76.90 | 9.02 | 29 | 77.69 | 7.79 | -0.359 | 0.721 |
| 60m | 11 | 72.36 | 5.63 | 10 | 77.00 | 9.90 | -1.336 | 0.197 |
| 90m | 5 | 72.20 | 6.53 | 0 | | | | |
| 120m | 4 | 71.00 | 5.77 | 0 | | | | |

Table 2: Between Group Comparison of Heart Rate at different time intervals

| Time | Group I (n=30) | | | Group II (n=30) | | | Student 't' test | |
|------|----------------|--------|-------|-----------------|--------|-------|------------------|--------|
| | N | Mean | SD | n | Mean | SD | 't' | 'p' |
| BL | 30 | 136.37 | 15.36 | 30 | 131.27 | 8.85 | 1.575 | 0.121 |
| BI | 30 | 130.70 | 16.37 | 30 | 124.77 | 9.64 | 1.711 | 0.092 |
| Int. | 30 | 144.80 | 14.27 | 30 | 128.37 | 15.36 | 4.293 | <0.001 |
| 1m | 30 | 132.33 | 17.57 | 30 | 119.63 | 14.94 | 3.016 | 0.004 |
| 3m | 30 | 131.27 | 17.58 | 30 | 116.67 | 14.30 | 3.529 | 0.001 |
| 5m | 30 | 124.13 | 16.50 | 30 | 120.03 | 13.27 | 1.061 | 0.293 |
| 10m | 30 | 124.27 | 16.50 | 30 | 122.47 | 13.55 | 0.462 | 0.646 |
| 15m | 30 | 127.70 | 19.25 | 30 | 128.07 | 12.67 | -0.087 | 0.931 |
| 30m | 30 | 133.63 | 15.13 | 30 | 129.57 | 16.32 | 1.001 | 0.321 |
| 45m | 30 | 134.67 | 12.24 | 29 | 130.07 | 15.48 | 1.268 | 0.210 |
| 60m | 11 | 134.55 | 10.26 | 12 | 129.08 | 19.12 | 0.842 | 0.409 |
| 90m | 5 | 129.00 | 9.03 | 0 | | | | |
| 120m | 4 | 131.50 | 0.58 | 0 | | | | |

Table 3: Between Group Comparison of Systolic BP at different time intervals

At all the periods of observation heart rate of patients of above two groups were found to be comparable. (BL-Base Line, BI- Before Intubation, I-At Intubation) except

at Intubation, 1 min & 3 min post intubation systolic BP of patients of Group- I was found to be significantly higher as compared to that of Group II.

| Time | Group I (n=30) | | | Group II (n=30) | | | Student 't' test | |
|------|----------------|-------|-------|-----------------|-------|-------|------------------|-------|
| | N | Mean | SD | n | Mean | SD | 't' | 'p' |
| BL | 30 | 74.03 | 10.21 | 30 | 75.13 | 8.37 | -0.456 | 0.650 |
| BI | 30 | 73.57 | 8.16 | 30 | 74.80 | 6.01 | -0.666 | 0.508 |
| Int. | 30 | 79.83 | 7.84 | 30 | 75.53 | 9.63 | 1.897 | 0.063 |
| 1m | 30 | 75.30 | 9.33 | 30 | 69.67 | 7.82 | 2.535 | 0.014 |
| 3m | 30 | 73.43 | 11.60 | 30 | 70.57 | 10.07 | 1.022 | 0.311 |
| 5m | 30 | 70.73 | 10.22 | 30 | 69.53 | 8.99 | 0.483 | 0.631 |
| 10m | 30 | 71.90 | 11.53 | 30 | 73.63 | 7.52 | -0.690 | 0.493 |
| 15m | 30 | 74.70 | 13.78 | 30 | 74.17 | 10.46 | 0.169 | 0.867 |
| 30m | 30 | 78.50 | 11.50 | 30 | 75.17 | 11.06 | 1.144 | 0.257 |
| 45m | 30 | 79.67 | 8.84 | 29 | 77.00 | 10.51 | 1.056 | 0.295 |
| 60m | 11 | 76.36 | 7.31 | 12 | 72.92 | 12.62 | 0.792 | 0.437 |
| 90m | 5 | 75.80 | 9.93 | 0 | | | | |
| 120m | 4 | 74.00 | 2.31 | 0 | | | | |

Table 4: Between Group Comparison of Diastolic BP at different time intervals

At 1 min post intubation diastolic BP of patients of Group I was found to be significantly higher as compared to that of Group II.

In Group I, statistically significant change in baseline DBP was observed only at Intubation, 30min, 45min post intubation. Range of change in baseline DBP in Group I was 0.63-7.83%.

In Group II, Change in baseline DBP was found to be statistically significant at 1min, 3min, and 5 min post-insertion. Range of change in baseline DBP in Group II was 0.04-7.45%.

| Time | Group I (n=30) | | | Group II (n=30) | | | Student 't' test | |
|------|----------------|--------|-------|-----------------|-------|-------|------------------|-------|
| | N | Mean | SD | n | Mean | SD | 't' | 'p' |
| BL | 30 | 98.67 | 10.38 | 30 | 95.27 | 7.66 | 1.444 | 0.154 |
| BI | 30 | 95.70 | 9.30 | 30 | 93.03 | 6.54 | 1.285 | 0.204 |
| Int. | 30 | 104.10 | 7.50 | 30 | 96.00 | 11.25 | 3.282 | 0.002 |
| 1m | 30 | 97.50 | 11.66 | 30 | 89.07 | 10.09 | 2.995 | 0.004 |
| 3m | 30 | 95.70 | 13.28 | 30 | 87.73 | 9.83 | 2.641 | 0.011 |
| 5m | 30 | 91.77 | 12.29 | 30 | 88.97 | 9.77 | 0.977 | 0.333 |
| 10m | 30 | 92.47 | 11.92 | 30 | 92.30 | 9.72 | 0.059 | 0.953 |
| 15m | 30 | 95.40 | 15.29 | 30 | 94.80 | 10.16 | 0.179 | 0.859 |
| 30m | 30 | 100.27 | 12.06 | 30 | 96.23 | 12.25 | 1.285 | 0.204 |
| 45m | 30 | 101.20 | 7.85 | 29 | 96.90 | 11.45 | 1.689 | 0.097 |
| 60m | 11 | 99.45 | 6.41 | 12 | 94.50 | 14.15 | 1.064 | 0.299 |
| 90m | 5 | 96.00 | 10.17 | 0 | | | | |
| 120m | 4 | 94.50 | 0.58 | 0 | | | | |

Table 5: Between Group Comparison of MAP at different time intervals

At intubation, 1 min & 3 min post intubation MAP of patients of Group I was found to be significantly higher as compared to that of Group II.

Range of change in baseline MAP in Group I was 0.83-6.99% and Group II was 0.47-7.53%.

| Time | Group I (n=30) | | | Group II (n=30) | | | Student 't' test | |
|--------|----------------|-------|------|-----------------|-------|-------|------------------|-------|
| | N | Mean | SD | n | Mean | SD | 't' | 'p' |
| Ins. | 30 | 15.20 | 9.52 | 30 | 20.47 | 13.34 | -1.760 | 0.084 |
| Pneum. | 30 | 12.70 | 7.11 | 30 | 16.53 | 7.31 | -2.060 | 0.044 |
| 10 m | 30 | 12.30 | 8.47 | 30 | 14.80 | 10.77 | -0.999 | 0.322 |
| 20 m | 30 | 13.13 | 8.10 | 30 | 14.73 | 8.51 | -0.746 | 0.459 |
| 30 m | 30 | 12.67 | 7.15 | 30 | 14.60 | 5.05 | -1.210 | 0.231 |
| 40 m | 30 | 14.23 | 6.31 | 29 | 12.41 | 3.94 | 1.324 | 0.191 |
| 50 m | 11 | 14.91 | 6.96 | 12 | 15.83 | 6.99 | -0.317 | 0.754 |
| 60 m | 11 | 14.36 | 8.05 | 12 | 12.58 | 5.79 | 0.613 | 0.547 |
| 90 m | 5 | 14.80 | 5.54 | 0 | | | | |
| 120 m | 4 | 18.00 | 3.46 | 0 | | | | |

Table 6: Between Group Comparison of Leak volume at different time intervals

Difference in Peak airway pressure of patients of above two groups was not found to be significant statistically at any of the above periods of observation but leak volume of patients of Group II was found to be significantly higher as compared to that of Group I (16.53±7.31 vs. 12.70±7.11 ml) at time of pneumoperitoneum. At rest of the time of observation, leak volume of patients of both the groups were found to be comparable.

| SN | Complication | Total (N=60) | Group I (n=30) | | Group II (n=30) | | Chi-square test | |
|----|------------------|--------------|----------------|------|-----------------|------|-----------------|-------|
| | | | No. | % | No. | % | χ ² | P |
| 1- | Cough/ST | 13 | 9 | 30.0 | 4 | 13.3 | 2.455 | 0.117 |
| 2- | Nausea/ Vomiting | 21 | 12 | 40.0 | 9 | 30.0 | 0.659 | 0.417 |
| 3- | Dysphonia | 6 | 4 | 13.3 | 2 | 6.7 | 0.741 | 0.389 |

Table 7: Between Group Comparison of Complications

None of the patient enrolled in the study had complication of laryngospasm, gastric insufflations, regurgitation, aspiration, blood on device and injuries. Most common complication observed by patients was nausea/vomiting (n=21; 35.0%) followed by cough/sore throat (n=13; 21.7%) and dysphonia (n=6; 10.0%), though all the above complications were found in higher proportion in patients of Group I as compared to Group II but these differences were not found to be significant statistically (p value = 0.417, 0.117, 0.389 respectively).

IV. Discussion

Among different innovative methods, I-gel airway device has been reported to be an easy to use and successful method for airway management even in low-skill settings. I-gel is a recently introduced device which is promoted as a simpler, faster and safer supraglottic airway device. Hence, the present study was planned with an aim to assess I-gel as an alternative to endotracheal tube in adult patients undergoing laparoscopic surgery with an intention to validate its clinical efficacy in our settings.

For this purpose, a prospective randomized-controlled study was carried out. To ensure that there is no induced bias owing to randomization, the age, gender, grade of surgery, anthropometry (weight, height and BMI), type of surgical procedure and baseline hemodynamic were also found to be statistically matched, i.e., the two groups (30 patients in each) did not have any induced bias owing to randomization.

In fact, the opinion regarding ease of insertion as observed in evidence based studies show a disparity. Suhitharan et al⁹ while comparing I-gel with LMAs also did not find a significant difference in ease of insertion. Massoud et al.¹⁰ on the other hand found that insertion of tube to be easier in ETT group as compared to I-gel group. Badheka et al¹². on the other hand, similar to our study, did not find a significant difference in ease of insertion between ETT and I-gel group. However, most of the studies that compared I-gel with ETT, similar to our study did not find a significant difference in ease of insertion.^{11,12,13,14}

In present study, mean time taken for insertion of airway device was 14.11±0.63 seconds in ETT group as compared to 9.88±0.79 seconds in I-gel group, thus showing that the insertion time was significantly lower in I-gel. Badheka et al.¹¹, Zanfaly et al.¹³ and Dhanda et al.¹⁵ found mean time taken for insertion to be lesser in I-gel as compared to ETT group. In fact, I-gel device is a relatively newer addition to the armamentarium of the anesthesiologist and we feel that the inconsistencies in insertion time could be controlled with adequate learning and mastering of I-gel airway device use.

In present study, during most of the intraoperative period, the hemodynamic parameters did not show a significant difference between I-gel and ETT groups. However, in general, the hemodynamic control was slightly better in I-gel group as compared to ETT group. Compared to results of present study, most of the other studies have found hemodynamic control to be better with I-gel as compared to ETT group^{10,11,12,16}. In present study, no significant difference in peak airway pressure was found between two groups at any of the observation periods, however, with respect to leak volume, we found it to be significantly lower in ETT as compared to I-gel

group at the time of attainment of pneumoperitoneum. As such, leakage parameters have been shown to be similar for both ETT and I-gel in different studies; however, there are some studies that have shown a better performance of I-gel as compared to ETT in trendelenburg position as compared to supine position¹⁴.

The findings of present study in effect showed I-gel to be a possible alternative to endotracheal tube. In fact, I-gel is reported to have an easy insertion, shorter insertion-time, better seal, lesser mucosal damage and reduced sympathetic activity resulting in hemodynamic stress.

V. Conclusion

On the basis of the study we conclude that I gel is a useful alternative to endotracheal tube in laparoscopic surgeries. I- gel has easy insertion, shorter insertion-time, better seal, lesser mucosal damage and reduced sympathetic activity resulting in hemodynamic stress with less complications as cough, sore throat, nausea/vomiting and dysphonia.

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