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Original Research Article

# Clinical Comparison of I Gel with Cuffed Et Tube during Abdominal Surgery

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**Conflict of interest: Nil**

**Abstract**

**Background:** The i-gel (Intersurgical Ltd) is a novel device that differs from other supraglottic airway devices in that it has a softer and a non-inflatable cuff. Our study was designed to assess whether the i-gel is suitable to provide pressure-controlled ventilation (PCV) during anaesthesia by measuring the gas leaks and comparing these values with that of the tracheal tube.

**Methods:** Total 40 patients, ASA I–II, were recruited to the study. Patients received a standard anaesthetic technique followed by an initial placement of the i-gel. The lungs were then ventilated at three different pressures (15, 20, 25 cm H2O) using PCV. The difference between the inspired and expired tidal volumes was used to calculate the leak volume. The leak fraction was defined as the leak volume divided by the inspired tidal volume. Following these observations, the i-gel was removed and replaced with the conventional tracheal tube and the recordings repeated.

**Results:** There was no significant difference between the leak fractions of the i-gel and the tracheal tube at 15 and 20 cm H2O PCV. At 25 cm H2O, the median difference in leak fraction was 0.02 (P - 0.014) and the median difference in leak volume was 26.5 ml (P - 0.006). There was no evidence of gastric insufflations with any of the pressures used during PCV.

**Conclusions:** We suggest that the i-gel can be used as a reasonable alternative to tracheal tube during PCV with moderate airway pressures.

**Keywords**: airway, equipment, i-gel, mechanical, ventilation



## Introduction

For spontaneously breathing patients, laryngeal mask airways (LMAs) are commonly utilised during anaesthesia. LMAs are also used to ventilate patients' airways during anaesthesia, but they may have a less effective seal than traditional tracheal tubes. [1] The i-gel (Intersurgical

Ltd, Wokingham, UK) is a novel supraglottic airway device (SAD) made of flexible, gel-like, and transparent thermoplastic elastomer. Contrary to the conventional LMA, it lacks an inflatable sleeve. Studies on cadavers have demonstrated that i-gels conformed effectively to the perilaryngeal anatomy and consistently obtained the correct positioning for supraglottic ventilation.[2] The insertion of the i-gel was substantially simpler compared to the insertion of other SADs, according to studies conducted on both manikins and patients.[3,4] In addition, there is evidence that it is simpler to train non-anesthesiologists on how to effectively insert i-gels compared to conventional SADs, making it a potentially useful device for situations such as resuscitation. [5,6] i-gel may also play a role in the management of problematic airways, as there have been reports of successful fiberoptic intubations performed with the aid of i-gel. [7,8] Recent studies support its use during anaesthesia in patients with spontaneous respiration. [9 -11] Currently, there are no published studies demonstrating that i-gel seals well during pressure-controlled ventilation (PCV). The purpose of our investigation was to determine if the i-gel is a suitable airway device for ventilating patients' lungs using PCV during anaesthesia. Our study aimed to determine whether i-gel sealing pressure and constricted tracheal tubes are equally effective airways during volume-controlled ventilation during involuntary abdominal surgery. This study seeks to evaluate and compare the cuffed endotracheal tube and i-gel regarding their: Difference in leak fraction between two airway devices before and after pneumoperitoneum with distinct tidal volumes, as well as a comparison of oropharyngeal leak pressure. Simple insertion: Attempts required to achieve optimal positioning

## Materials & Methods:

Study type: Prospective, randomised, double-blind study.

Study area: Anesthesia department and Surgery department of tertiary care hospital of Gujarat

Sample size: The sample size was calculated to be 40 in each group with α error of 0.05 and power of 90% considering a difference in the LF of more than 16% to be significant.

Study population: After obtaining written consent and Institutional Ethics Committee approval, patient aged 18- 65 years of age were enrolled in the study.

### Inclusion criteria:

- ASA grade I or II,
- Body mass index (BMI) between 25 and 30 kg/m2.
- Patients were scheduled to undergo a variety of elective surgical procedures with an anticipated duration of less than 2 hours.

### Exclusion criteria:

- Any significant acute or chronic lung disease,
- Inadequate cervical mobility/cervical malformation,
- Known/anticipated difficult airway/reduced mouth opening/disease of oral cavity,
- Full stomach/increased risk of aspiration (GERD, hiatal hernia, diabetes mellitus),

**Methodology:** The patients were premedicated with 2 g kg-1 of intravenous fentanyl, anaesthesia was induced with 1.5-2 mg kg-1 of propofol, and muscle relaxation was obtained with 0.6 mg kg-1 of rocuronium and confirmed using a train-of-four stimulation count (TOF=0). The ETT cuff was inflated to 25 cm H2O using a hand-held aneroid pressure gauge, and placement was confirmed by capnography and chest auscultation. After computer-

generated randomization, patients were assigned to Group I or Group E, where I gel or tethered ETT were used, respectively, for airway management. I-gel size 3 for 30–60 kg, size 4 for 50–90 kg, and size 5 for >90 kg. ETT sizes of 8.5 mm ID for men and 7.5 mm ID for women were utilised. Insertion time was measured as the interval between the insertion of i-gel into the mouth or the insertion of the laryngoscope blade into the mouth and the appearance of the first square waveform on the capnograph. The respective timings for each 'attempt' would be T1, T2, and T3. Adding T1, T2, and T3 would have yielded the effective airway time. We defined 'insertion failure' as more than three abortive attempts, in which case the airway would have been secured at the discretion of the senior anesthesiologist supervising the case.

PCV was then maintained at a pressure lower than the device's leak pressure in Group I (15, 20, 25 cm H2O) and in Group E (20 cm H2O) at a rate adapted to maintain EtCO2 in the range of 30–40 mm Hg. After thirty minutes, the LF was recalculated using pressures of 15, 20, and 25 cm H2O, with measurements taken over ten breaths for each pressure setting. At the conclusion of the operation, any blood stains on the laryngoscope, tracheal tube, or i-gel were recorded. Each patient had complications during insertion, maintenance, and removal. The primary outcome of our study was the difference in LF between the two investigated airway devices. Secondary outcomes included LV differences, airway leak pressures, success of first attempt insertion, and complications.

Statistical analysis: Qualitative data was described in frequency and percentage and compared using Chi square test. Quantitative data (LF, LV, airway leak pressures and time of insertion) were analysed using unpaired t test. P value < 0.05 was considered as significant.

## Results

**Table 1: Baseline characteristics of study participants**

| Age Range | IGEL | ETT | P value |
|---|---|---|---|
| 20-29 | 12 | 10 | 0.903 |
| 30-39 | 8 | 8 | |
| 40-49 | 7 | 6 | |
| 50-60 | 13 | 16 | |
| **Gender** | | | |
| Male | 10 | 12 | 0.525 |
| Female | 10 | 8 | |
| **ASA Grade** | | | |
| I | 25 | 21 | 0.365 |
| II | 15 | 19 | |

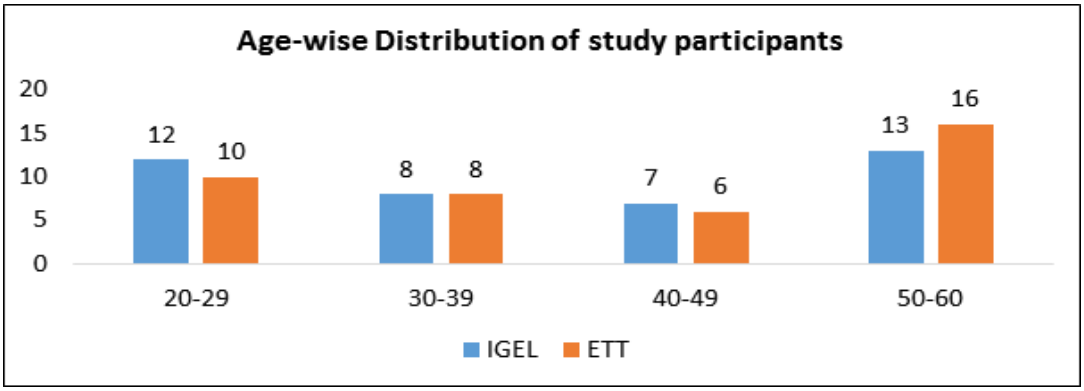


**Figure 1: Age-wise distribution**

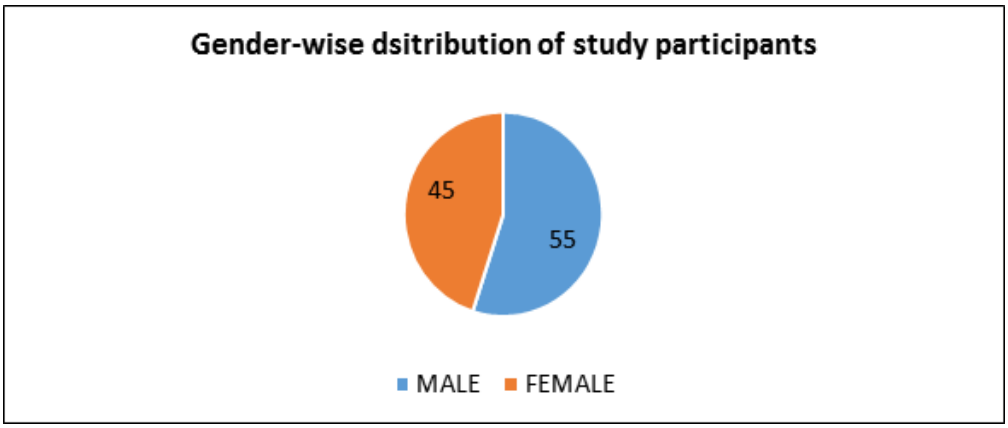


**Figure 2: Gender-wise distribution**

**Table 2: Airway characteristics of the patients**

| Airway Characteristics | | I-GEL | ETT | P Value |
|---|---|---|---|---|
| Mouth Opening | < 5 CM | 9 | 11 | 0.605 |
| | ≥5 CM | 31 | 29 | |
| Thyromental Distance | < 6 CM | 9 | 8 | 0.784 |
| | ≥6 CM | 31 | 32 | |
| Mallampati Grade | 1 | 8 | 7 | 0.774 |
| | 2 | 32 | 33 | |

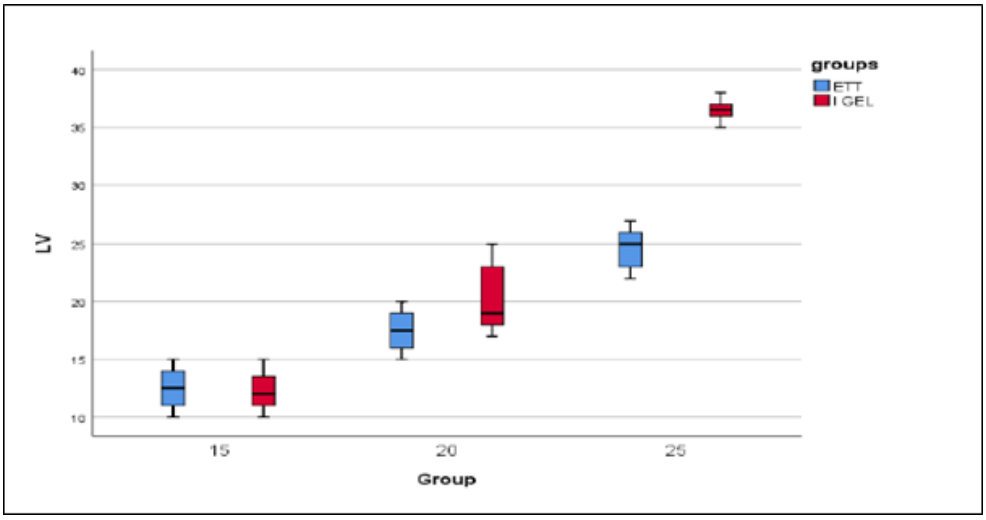


**Figure 3: Boxplot of leak volume (LV) for the i-gel and the tracheal tube (tt)**

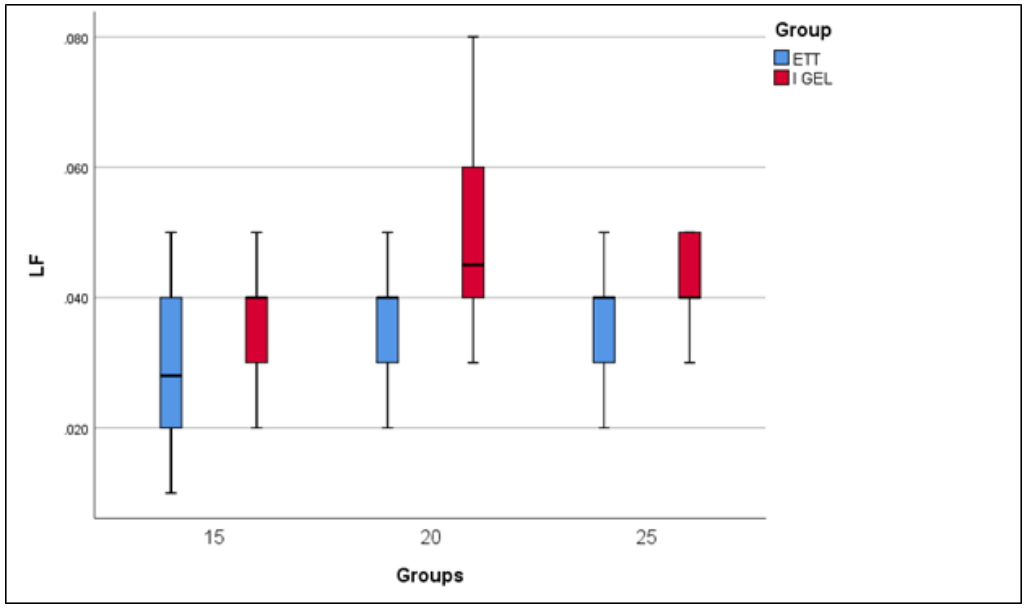


**Figure 4: Boxplot of leak fraction (LF) for the i-gel and the tracheal tube (tt)**

## Discussion

Recently, there has been a trend towards substituting a SAD for a tracheal tube in patients with a low risk of aspiration when performing controlled ventilation. Using a SAD as opposed to a tracheal tube has numerous well-established advantages. The 40 patients participating in the study were distributed equally amongst the group (I Gel and ET Tube). Comparison of the number of patients in different age intervals was done. the mean age for the I-Gel group was 40.2 ± 13.3 years and for the ET Tube group it was 42.9 ± 12.1 years. The airway characteristics of the patients studied i.e. mouth opening, thyromental distance and the Mallampati score were also noted the results were not statistically significant.

The i-gel is a relatively novel SAD constructed from a gel-like material and lacking an inflatable cuff. It is intended to further reduce airway morbidity. The absence of an inflatable cuff could conceivably increase the likelihood of gas leakage during PCV. No significant difference in gas leakage was found between the use of an i-gel and a tracheal tube during PCV with moderate airway pressures, according to the results of our study. Conventionally, the tracheal tube is used to ventilate patients' airways during anaesthesia; therefore, any alternative device should be compared to this gold standard. Uppal et al. [12] found leak pressure for i-gel 28 (20–35) cm H2O by both auscultation and manometer stabilization methods. In our study we concluded that airway leak pressure for i-gel was 26 cm H2O. Ishwar et al. [13] concluded that airway leak pressure for i-gel was 25.27 cm H2O using same methods.

Lu et al. [14] compared Pro-Seal laryngeal mask airway (PLMA) with Classic laryngeal mask airway (LMA) for positive pressure ventilation during laparoscopic cholecystectomy. They concluded that PLMA is more effective ventilator device for laparoscopic cholecystectomy than classic LMA.

As the quantity of leak volume is affected by the pressure generated between the airway device and supraglottic tissues, in this study we ventilated the patients' lungs using pressure-controlled mode as opposed to volume-controlled mode. In addition, there are indications that PCV is more effective and safer than volume-controlled ventilation for controlled ventilation in SAD. [15] The i-gel obtained a median airway leak pressure of 28 cm H2O, which

is greater than that of the conventional LMA (20 cm H2O) and comparable to that of the Proseal LMA.20 During our study, there was no evidence of gastric insufflations, regurgitation, or aspiration while using i-gel for PCV. There were no unsuccessful insertions.

In our investigation, the incidence of visible blood on the i-gel after removal was 12% (5/40). This is comparable to the symptoms of other SAD. The incidence of visible blood in other studies conducted was been estimated to range from 12 to 18 per cent with the use of SAD, depending on the type of SAD, insertion technique, and convenience of insertion. [16,17] Possible limitations of our study we did not investigate pressures greater than 25 cm H2O that may be related to laparoscopic procedures.

## Conclusion

Our study supports the use of i-gel for PCV if pressures can be limited to 25 cm H2O; however, a small percentage of patients may experience significant gas leakage. Attempts should be made to identify these using spirometry shortly after insertion; if the gas escapes are excessive, the i-gel should be replaced with a different device.

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