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Anaesthesia Section

# Comparison between Polyvinyl Chloride and Flexometallic Endotracheal Tube for Blind Tracheal Intubation through I-gel: A Randomised Clinical Study

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## ABSTRACT

**Introduction:** I-gel is the most commonly used, second-generation supraglottic airway device, which plays an important role in modern anaesthesia practice as a rescue device in difficult as well as failed intubation situations and resuscitations. Now-a-days, it is gaining popularity as a conduit to facilitate endotracheal intubation. No Endotracheal Tube (ETT) is designed specifically for intubation through I-gel. The ETT used for routine tracheal intubation are standard Polyvinyl Chloride (PVC) ETT and Flexometalic ETT.

**Aim:** To compare the two different types of ETTs i.e. standard PVC ETT and Flexometatlic ETT for blind tracheal intubation through I-gel.

**Materials and Methods:** The present study was a single-blinded, randomised clinical trial in which 120 patients were randomly allocated into two groups on the basis of the ETT used for intubation through I-gel. In group P blind tracheal intubation was done using PVC ETT, and in group F blind tracheal intubation was done using Flexometatlic ETT through I-gel. Time taken for successful intubation, number of successful intubations, ease of intubation, number of attempts, manoeuvers used, and complications were recorded. Quantitative variables were compared using an independent t-test and qualitative variables were compared using the Chi-square test.

**Results:** The mean time taken for successful intubation in group P was 22.31±3.771 sec and in group F was 26.51±4.408 sec ($p<0.001$). Intubation was significantly easy (26/60 vs 13/60) with PVC ETT ($p=0.011$). More patients were successfully intubated with PVC ETT than Flexometalic ETT (48/60 vs 36/60; $p=0.017$).

**Conclusion:** Polyvinyl Chloride Endotracheal Tube (PVC ETT) is a better choice for blind tracheal intubation through I-gel as compared to flexometallic ETT.

**Keywords:** Blind tracheal intubation, Ease of intubation, Endotracheal tubes, Supraglottic airway device

## INTRODUCTION

Airway protection is the primary responsibility of the anesthesiologist in the safe administration of anaesthesia and the gold standard method for protecting the airway is tracheal intubation with ETT. However, the success rate of intubation varies according to the patient's airway structure for which there may be a failure of tracheal intubation. The Supraglottic Airway Devices (SADs) developed as an alternative airway management strategy [1]. Since 1988, many SADs are introduced in anaesthesia practices and are commonly used as airway adjuncts during anaesthesia in selected elective cases, where it allows both controlled ventilation and spontaneous ventilation and now-a-days are helpful in managing anticipated and unanticipated difficult and failed tracheal intubation situations [2]. In response to difficulties found when attempting to insert ETT blindly into the trachea through the Classic Laryngeal Mask Airway (LMA), intubating LMA/Fastback was introduced in 1997. It was designed as a conduit for blind ETT intubation. Moreover, there is an ETT designed specifically for intubation through intubating LMA [3,4]. Over the years, ILMA has been used as the standard SAD as the conduit for tracheal intubation [5-7].

I-gel is a newer, anatomically designed, second-generation SAD invented in 2007. Now-a-days it has become the most popular SAD in anaesthesia practices for its ease and speed of insertion. The shape of its cuff is the mirror image of laryngeal anatomy providing a better seal to the larynx, allowing successful controlled ventilation with less chance of aspiration in inexperienced users [8]. It is not designed for intubation like ILMA but it has been used for intubation because of its large bowel with the absence of aperture bars, and short wider diameter of the ventilating tube which allows direct passage of an ETT through it than the other SADs [9]. Many studies concluded the high intubation success rate through I-gel guided by fiberoptic bronchoscope [10-13]. Intubation using a fiberoptic bronchoscope is not always possible as it is not available everywhere, especially in developing countries like India. Some studies were also conducted on blind tracheal intubation through I-gel [14-19]. As I-gel was not designed as a conduit for intubation, there is no ETT designed specifically for intubation through I-gel. Also, no information has been provided by the manufacturer about the type of ETT suitable for intubation while it is used as a conduit for intubation.

Generally, for routine intubation, standard PVC and Flexometalic ETT are used. The present clinical trial aimed to compare blind intubation through I-gel using two different types of ETT i.e., PVC ETT and Flexometalic ETT. The primary objectives were the time taken for intubation and the number of successful tracheal intubations. Secondary objectives were the ease of intubation, number of attempts, maneuvers used, and postoperative complications.

## MATERIALS AND METHODS

The present study was a single-blinded, randomised clinical trial carried out after approval of the Institutional Ethics Committee (IEC) (approval no-19266/Dt-20.02.20/IST-198/19). The study was conducted in Department of Anaesthesiology at Veer Surendra Sai Institute of Medical Sciences and Research, Sambalpur, Odisha, India (tertiary Medical centre), from February 2020 to November 2021. This study was registered in the Clinical Trial Registry India (CTRI/2021/10/037646).

**Sample size calculation:** Based on the result of the time required for intubation with PVC and Flexometalic ETT(10.51±3.82 seconds vs 12.79±4.91 seconds) in a study by Choudhary N et al., [20] the sample size was calculated using the formula for two means: $n=[(\sigma_1^2+\sigma_2^2/K)(Z_{1-\alpha/2}+Z_{1-\beta})^2]/(\mu_1-\mu_2)^2$, with a 95% confidence interval and power of 80%. The minimum sample size required for each group was 56. Considering attrition, 60 patients were recruited in each group.

**Inclusion criteria:** One hundred and twenty patients of age group between 18-60 years, American Society of Anaesthesiologists (ASA) grade I and II, of 40-70 kg bodyweight belonging to both sexes, with Mallampati scores 1 and 2, mouth opening >3 cm undergoing elective surgery under general anaesthesia requiring endotracheal intubation were included in the study.

**Exclusion criteria:** Patients with an anticipated difficult airway, oropharyngeal mass, neck swelling, postburn contracture neck, Body Mass Index (BMI) <18 or >30 kg/m$^2$, patients with risk of aspiration i.e. pregnancy, hiatus hernia, gastroesophageal reflux disease, patients with obstructive and restrictive lung diseases, where the use of muscle relaxants is contraindicated, patients who refused to participate were excluded from the study.

The patients were randomly assigned, using a random number table, into two groups of 60 each, that is, group-P and group-F. Patients were blinded to the type of ETT used.

- **Group P:** Blind intubation was done through I-gel using a PVC ETT.
- **Group F:** Blind intubation was done through I-gel using a Flexometalic ETT.

### Procedure

During the preanaesthesia check-up, every patient was explained about the study, informed written consent was obtained and willingness to participate in the study was documented. All the patients were kept nil per orally for 8 hours before surgery. Ranitidine 50 mg Intravenous (i.v.), and Metoclopramide 10 mg i.v. was given 30 minutes before the patient was shifted to the operation theatre. In the operation theatre, a multipara monitor showing Heart Rate (HR), Non Invasive Blood Pressure (NIBP), Electrocardiogram (ECG), oxygen saturation ($SpO_2$), and End-tidal Carbon Dioxide ($EtCO_2$) was attached to the patient and intravenous fluid of Ringer's lactate or normal saline solution was started.

The size of the I-gel was selected based on the patient's body weight in accordance with the manufacturer's recommendations. I-gel size 3 was used for weight between 30 to 50 kg and size 4 was used for weight between 50 to 70 kg. Both PVC and Flexometalic type ETT of size 6.5 mm Internal Diameter (ID) and 6 mm (ID) were selected for I-gel size 3 and sizes 7 mm (ID) and 6.5 mm (ID) were selected for I-gel size 4. I-gel and two different sizes of ETT according to the size of I-gel, were lubricated with water-based jelly.

Five minutes before induction premedication of glycopyrrolate 0.004 mg/kg i.v., midazolam 0.03 mg/kg i.v., nalbuphine 0.2 mg/kg i.v., and Ondansetron 0.1 mg/kg i.v., was given to the patient and preoxygenated with 100% oxygen. Xylocard 1.5 mg/kg i.v. was given to attenuate the haemodynamic response to tracheal intubation and to reduce pain during propofol injection. Anaesthesia was induced with Propofol 2 mg/kg i.v. After confirmation of adequate ventilation, vecuronium 0.1 mg/kg i.v. was given for muscle relaxation. When the jaw was relaxed the appropriate size I-gel according to the weight of the patient was inserted keeping the head in a sniffing position. If any difficulty was experienced, the position was adjusted by applying manipulations like jaw thrust, chin lift, head extension, flexion, and in or out movements of the device. The correct position and ventilation adequacy was confirmed by the appearance of a square wave capnograph trace, chest expansion equally on both sides on the gentle application of intermittent positive pressure ventilation, no audible oropharyngeal leak, and stable oxygen saturation. If required, use of the different size of SAD was attempted. A maximum of three times were attempted for placement of I-gel before it was considered a failure. Then for intubation according to the group randomisation, appropriate size ETT 6.5 mm (ID) ETT for I-gel size 3 and 7 mm (ID) ETT for I-gel size 4 was passed through the ventilating tube of I-gel. Successful intubation was confirmed by bilateral chest expansion and square wave capnograph.

A maximum of three attempts were allowed to intubate the patient. During the 1st attempt of ETT insertion, if resistance was felt, different manoeuvers like gentle rightward, leftward displacement of the larynx, and cricoid pressure were applied externally and 90° counter-clockwise rotation of the ETT was done to align the bevel. ETT was tried to insert once during each type of manoeuvers. In the 2nd attempt, a lesser size of ETT was used without manoeuvres. In the 3rd attempt, the same manoeuvers that were used during the 1st attempt were repeated. After confirmation of intubation, the SAD was removed using a smaller size tube as stabilising rod and anaesthesia was maintained as per the institutional protocol. If intubation was not possible in three attempts, intubation was done with direct laryngoscopy and the patient was excluded from the study. During intubation, if any time $SpO_2$ decreased to ≤92%, ventilation was done through I-gel till it reaches 100%. Haemodynamic parameters were noted for the duration of 10 min after intubation. All the SADs insertions and intubations were done by the same anaesthesiologist who had already gained experience with blind intubation in 20 patients with both types of ETTs through I-gel before the study.

The parameters recorded were-

- The I-gel insertion time- the time from holding the I-gel in hand to the appearance of the first capnography waveform.
- Intubation time- the time from starting insertion of the ETT to the first successful breath confirmed by capnography waveform. In more than one attempt, a sum of all attempts excluding time interval between attempts.
- The number of successful intubation attempts.
- Ease of intubation (easy- intubation in the first attempt without any manoeuver, slight difficulty-intubation in the first attempt with manoeuver, difficult- intubation done in 2nd and 3rd attempts, failure- intubation not possible in three attempts).
- Trauma to the airway- the presence of blood on the tube and I-gel after removal of the device.
- Sore throat and hoarseness were assessed after 2 hours in the postoperative period.

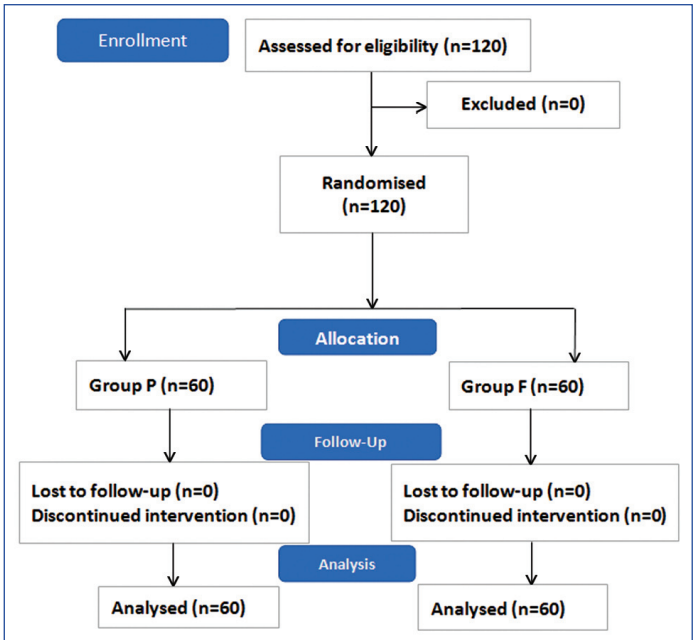
## STATISTICAL ANALYSIS

The data were analysed using Statistical Package for the Social Science (SPSS) statistical software version 23.0. Quantitative variables were compared using an Independent t-test and qualitative variables were compared using the Chi-square test. A p-value of ≤0.05 was considered statistically significant.

## RESULTS

A total of 120 patients were enrolled in the study and all completed the study without any dropouts [Table/Fig-1]. Patients' demographic and anthropometric data were similar between both groups [Table/Fig-2]. I-gel placement was 100% successful in both groups. The insertion time (p-value=0.135), the number of attempts (p-value=0.432) for I-gel placement, and the duration of surgery (p-value=0.445) were comparable in both groups [Table/Fig-3].

The mean time required for all successful intubations was significantly less in group P than in group F. The mean time required for successful intubation at the first attempt was significantly lesser for group P than for group F. The total number of successful intubations was 48/60 (80%) in group P and 36/60 (60%) in group F.




**[Table/Fig-1]:** CONSORT flow chart.

| Variables | Group P (PVC tube) (n=60) | Group F (Flexometalic tube) (n=60) | p-value |
|---|---|---|---|
| **Age (years)** | 36.70±6.958 | 37.55±7.975 | 0.535 |
| **Sex, n (%)** | | | |
| Male | 46 (76.67) | 41 (68.33) | 0.307 |
| Female | 14 (23.33) | 19 (31.67) | |
| **Weight (kgs)** | 55.08±6.45 | 56.400±6.50 | 0.268 |
| **BMI (kg/m²)** | 22.73±2.83 | 23.038±2.80 | 0.561 |
| **ASA grade, n (%)** | | | |
| 1 | 51 (85) | 48 (80) | 0.471 |
| 2 | 9 (15) | 12 (20) | |
| **Mallampati score, n (%)** | | | |
| 1 | 43 (71.67) | 47 (78.33) | 0.399 |
| 2 | 17 (28.33) | 13 (21.67) | |
| **Mouth opening (cm)** | 4.31±0.25 | 4.292±0.28 | 0.662 |
| **Thyromental distance (cm)** | 6.48±0.10 | 6.448±0.10 | 0.078 |

**[Table/Fig-2]:** Patients demographic data.
p-value <0.05 was statistically significant

| Variables | Group P (PVC tube) (n=60 | Group F (Flexometalic tube) (n=60) | p-value |
|---|---|---|---|
| **I-Gel insertion attempts, n (%)** | | | |
| 1 | 50 (83.33) | 53 (88.33) | 0.432 |
| 2 | 10 (16.67) | 7 (11.67) | |
| 3 | 0 | 0 | |
| **Insertion time (sec)** | 13.18±2.58 | 13.883±2.50 | 0.135 |
| **Duration of surgery (mins)** | 57.48±10.53 | 56.050±9.93 | 0.445 |

**[Table/Fig-3]:** Success rate and time taken for I-gel airway insertion and duration of surgery.
p-value <0.05 was statistically significant

The number of successful intubations at the 1st attempt in group P and group F was 34/60(56.67%) and 27/60(45%), respectively. There was a statistically significant difference in the ease of intubation (p-value=0.011) and the number of successful intubation attempts (p-value=0.036) in both groups. Oesophageal intubation was statistically more in group F. Blood on the device and sore throat were comparable in both groups [Table/Fig-4,5]. Both the groups had a non significant rise in HR and blood pressure during intubation through I-gel.

| Variables | Group P (PVC tube) (n=60) | Group F (Flexometalic tube) (n=60) | p-value |
|---|---|---|---|
| **Total Intubation time (sec)** | 22.31±3.77 | 26.519±4.40 | <0.001* |
| **Intubation time when the first attempt was successful (sec)** | 20.54±3.00 | 23.573±2.81 | <0.001* |
| **Number of total successful intubations, n (%)** | | | |
| Successful | 48 (80) | 36 (60) | 0.017* |
| Failed | 12 (20) | 24 (40) | |
| **Successful intubations in 1st attempt No (%)** | 34 (56.67) | 27 (45) | 0.201 |
| **Number of attempts for successful intubation, n (%)** | | | |
| 1st attempt | 34 (56.67) | 27 (45) | 0.036* |
| 2nd attempt | 12 (20) | 3 (5) | |
| 3rd attempt | 2 (3.33) | 6 (10) | |
| **Ease of intubation, n (%)** | | | |
| Easy | 26 (43.33) | 13 (21.66) | 0.011* |
| Slight Difficult | 8 (13.33) | 14 (23.33) | |
| Difficult | 14 (23.33) | 9 (15) | |
| Failed | 12 (20) | 24 (40) | |
| **Manoeuvres done, n (%)** | | | |
| Yes | 34 (56.67) | 47 (78.33) | 0.011* |
| No | 26 (43.33) | 13 (21.67) | |

**[Table/Fig-4]:** Parameters evaluated during tracheal intubation through I-Gel.
*p-value <0.05 was statistically significant

| Variables | Group P (PVC tube) (n=60) | Group F (Flexometalic tube) (n=60) | p-value |
|---|---|---|---|
| Oesophageal intubation, n (%) | 4 (6.67) | 13 (21.67) | 0.034* |
| Bloodstain on I-Gel/ETT, n (%) | 9 (15) | 6 (10) | 0.408 |
| Sore throat, n (%) | 10 (16.67) | 6 (10) | 0.283 |

**[Table/Fig-5]:** Complications observed during blind tracheal intubation through I-Gel.
*p-value <0.05 was statistically significant

## DISCUSSION

I-gel is a novel Supraglottic Airway Devices (SADs) originally designed for ventilation, widely used for elective surgeries in selected cases, and now-a-days adopted as an alternative approach for intubation. Under fiberoptic guidance tracheal intubation through I-gel, a high success rate of intubation of 100%, 96.6%, 100%, and 93.33% was reported by published studies [10-13]. However, a variable successful intubation rate was observed for blind tracheal intubation through I-gel. Blind intubation using PVC ETT through I-gel was conducted by Bhandari G et al., [18] Kapoor S et al., [19] and Halwagi A et al., [16] and reported the total successful intubation rate and 1st attempt successful intubation rate of (78.33% and 65.55%), (82% and 66%) and (73% and 69%) respectively. Blind intubation using a Flexible Silicon Tube (FST) (which was used for intubation via ILMA) through I-gel was conducted by Naik L et al., [21] and reported an overall success rate of 58.3% and 1st pass success rate of 36.67%. The low success rate of intubation with FST, maybe due to the soft and straight body of the tube, which exits from the I-gel in a less anterior angulation making it difficult to pass into the laryngeal inlet. However, Choudhary B et al., observed a success rate of 75% when conducting blind intubation through I-Gel using Intubating Laryngeal Mask (ILMA) ETT [22].

In this study, the total number of successful intubations was significantly high with PVC ETT (80%) than with Flexometalic ETT (60%). In case of intubation with PVC ETT, out of 80% of successful intubations, 26/60 (43.33%) cases were intubated easily without any manoeuvers, 8/60 (13.33%) cases were intubated with slight

difficulty using manoeuvers, 14/60 (23.33%) cases were intubated with difficulty in 2nd and 3rd attempts using one size down of ETT and in 12/60 (20%) cases, tracheal intubation was failed even after manoeuvers. In case of intubation with Flexometalic ETT, intubation was successfully done in 60% of cases, out of which 13/60 (21.67%) cases were intubated easily, 14/60 (23.33%) cases were intubated with slight difficulty, 9/60 (15%) cases were intubated with difficulty and 24/60 (40%) cases were failed even after manoeuvers. Thus, the intubation was significantly easier with PVC ETT than with Flexometalic ETT.

The number of successful attempts for intubation was significantly more with PVC ETT compared to Flexometalic ETT. But the 1st attempt success rate was comparable in both the groups (56.67% vs 45%). This may be because, the rigid body and anteriorly fixed curvature of the PVC tube, make it align towards the laryngeal inlet while exiting through the I-gel, making it easy to intubate while the soft, floppy, straight Flexometalic ETT exit in a straight line when comes out from the I-gel, making it difficult to pass into the laryngeal inlet and thus less number of ease of intubation. But when authors used manoeuvers like cricoid pressure, laryngeal displacements and 90° counter-clockwise rotation, the number of intubations was increased and the total number of 1st attempts of successful intubation was increased. The 90° rotation was easy with Flexometalic ETT as it is straight but difficult with PVC ETT as it is curved and to rotate it, authors had to remove the ETT upto the distal end of the I-gel. So the success rate was increased with the Flexometalic ETT with manoeuvers. In the 2nd attempt with decreasing the size of ETT, the success rate was increased with PVC ETT, as the resistance decreases when it passes through I-gel, but in the case of Flexometalic ETT due to its soft and straight nature, the number of oesophageal intubations increased.

Similar findings were reported by Choudhary N et al., who conducted blind tracheal intubation through I-gel using three different types of ETT. They found that the overall success rate and 1st attempt success rate were highest with PVC ETT (88% and 68%) compared to Flexometalic ETT (76% and 52%) and ILMA ETT(72% and 48%). Their higher success rate was because, before the blind intubation through the I-gel, they used a fiberoptic bronchoscope to grade the glottis view through the I-gel and intubated when proper placement of I-gel was confirmed with a Brimacombe score of 3 or 4 [20]. In the present study, 1st attempt success rate was comparable as we have used manoeuvers during 1st attempt but they have not used manoeuvers in the 1st attempt. Theiler L et al., compared two endotracheal tubes (FST vs McGill PVC ETT) through I-gel and ILMA in predictable difficult airways, observed a low success rate of 15% with McGill PVC tube and 21% with FST tube, which maybe due to the presence of difficult airway [23].

The mean time required for total successful intubation and the mean time required for intubation at 1st attempt was significantly shorter with PVC ETT than with Flexometalic ETT. The time required for intubation was more for Flexometalic ETT because more number of cases required manoeuvers for successful intubation. Choudhary N et al., found that intubation time was lesser with PVC ETT (10.51±3.82 sec) than with Flexometalic ETT (12.79±4.91 sec) during intubation via I-Gel [20]. In this study, the time required for total successful intubation and the mean time required for intubation at 1st attempt with PVC ETT was 22.31±3.77 sec and 20.54±3.00 sec respectively. Nearly similar intubation times for blind tracheal intubation with PVC ETTthrough I-Gel were reported by Bhandari G et al., [18] (the total successful intubations time and 1st attempt time were 29.63±1.39 sec and 18.73±1.41 sec respectively) and Halwagi A et al., [16] (the total intubation time was 22±13 sec).

The study conducted by Choi HY et al., on the manikin simulation, demonstrates that the PVC tube shows a similar intubation time to the Wire-Reinforced Silicone (WRS) tube in I-gel blind intubation. They explained that the WRS tube can be more advantageous than the PVC tube because the WRS tube is more flexible and non compressible during the passage through I-gel. However, this may be due to the absence of anatomical variations in manikin's airway as seen in the natural airway in human beings [24].

In this study, esophageal intubation with PVC ETT occurred in 6.67% (4/60) compared to 21.67% (13/60) with Flexometalic ETT (p-value=0.034). Lip trauma and dental trauma were not seen in any patients. Airway trauma was seen more with PVC ETT (9/60) than Flexometalic ETT (6/60) but, was not statistically significant. Choudhary N et al. found a statistically significant incidence of oesophageal intubation with Flexometallic ETT and ILMA ETT compared to PVC ETT. They found the incidence of injury was more with PVC ETT, which was also found to be statistically and clinically insignificant [20].

The postoperative sore throat was comparable in both groups and hoarseness was not complained by anyone. There was a non-significant rise in HR and MAP to ETT intubation through I-gel in both groups, returning to baseline after 5 minutes. Desaturation was not reported in any patient.

### Limitation(s)

In the present study, the patients with normal airways and ASA grade-1 were enrolled, hence findings cannot be applied to patients with anticipated difficult airways and critically ill patients. Due to the unavailability of the fiberoptic bronchoscope, the position of the I-gel in relation to the laryngeal structures could not be visualised. This would have been better as it helps in visualising the proper alignment of I-gel, and placement of ETT into the trachea. Blinding of the anaesthesiologist for administering the I-gel and ETT was not possible. So further studies taking geriatric, higher ASA grade, and difficult airways are warranted to know the insertion condition and haemodynamic conditions.

## CONCLUSION(S)

The number of successful blind tracheal intubations through I-gel, was more with PVC ETT than Flexometalic ETT. Blind tracheal intubation through I-gel using PVC ETT took less time to intubate, was easy to intubate, and required fewer manoeuvers for intubation compared to intubation using Flexometalic ETT. Hence, PVC ETT is better in comparison to Flexometalic ETT for blind tracheal intubation using I-gel as a conduit.

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