ORIGINAL ARTICLE

A Comparative Study of I-gel with Endotracheal Tube for Pressure Controlled Ventilation

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Abstract:

Background: Endotracheal intubation is considered to be the benchmark for controlled ventilation during general anaesthesia. But supraglottic airway devices are taking the place of endotracheal tubes in many scenarios and i-gel is one such airway device. *Aim and Objectives:* To assess whether i-gel is comparable to endotracheal tube for pressure controlled ventilation at different inspiratory pressures. *Material and Methods:* Forty American Society of Anaesthesiologists (ASA) I-II patients undergoing elective surgery were selected. Following induction, airway was secured with i-gel. Pressure controlled ventilation was initiated at four different pressures (10, 15, 20, 25 cm of H_2O). Inspiratory and expiratory tidal volumes were measured and leak volume was calculated as the difference of the two. Leak fraction was calculated by dividing leak volume by inspiratory tidal volume. Then i-gel was withdrawn, patient was intubated and the measurements repeated. Statistical analysis was done using two-tailed student's t test. *Results:* There was no significant difference on comparing the leak volume and leak fraction in the two groups at 10, 15 and 20 cm of H_2O. However, at 25 cm of H_2O, there was statistically significant difference in leak volume and leak fraction between the two groups. *Conclusion:* I-gel can be considered as a safe alternative to endotracheal tube for pressure controlled ventilation at moderate pressures during anaesthesia.

Keywords: Airway leak test, Inspiratory airway pressure, Supraglottic airway devices, Tracheal intubation

Introduction:

Maintenance of airway plays a major role in general anaesthesia. The gold standard device used for this purpose is Endotracheal Tube (ETT). Supraglottic Airway Devices (SADs) are slowly replacing ETTs in many scenarios [1-4]. But the major disadvantage of SADs is that it provides less effective seal when compared to ETTs. I-gel is a supraglottic airway device that provides an effective seal [5-6]. This is because it is made of thermoplastic elastomer and it conforms to perilaryngeal anatomy. It also has a non-inflatable cuff. I-gel serves as an ideal airway maintenance device by reducing tissue damage and it is easy to insert during resuscitation [4, 7-10]. The minimal tissue damage is due to the absence of the inflatable cuff [1, 11-14]. SADs are used for Volume Controlled Ventilation (VCV) more commonly than for Pressure Controlled Ventilation (PCV) during anaesthesia in regular practice. But literature shows that all SADs including i-gel are more efficient and safer for PCV [15-16]. Although i-gel has been in use for just more than a decade, there are very few studies conducted with i-gel for PCV during anaesthesia. In our study, we compared the effectiveness of seal in terms of gas leaks, ease of insertion and the incidence of tissue trauma between i-gel and endotracheal tube during PCV.

Material and Methods:

Forty patients of either gender scheduled for elective surgery were considered for the study after approval from the Institutional Ethics Committee. Written informed consent was obtained from all patients. Our study, which is a cross over quasi experimental study, was conducted at Medical Trust Hospital, Kochi, Kerala in the time period of 2010 to 2012. The patients included in the study were posted for hernia repair, laparoscopic appendicectomy or cholecystectomy. Patients belonging to ASA I-II category and age group of 16 to 70 years were enrolled. Patients having acute/chronic respiratory disease, abnormal anatomy of neck and respiratory tract, obesity, increased risk of aspiration, children and pregnant women were excluded.

Datex- Ohmeda/ Aespira 7100 anaesthesia machine which has a built-in pressure gauge was used in inducing anaesthesia and also for the airway leak test. Servo iMaquet ventilator was used to measure the Inspiratory and Expiratory Tidal Volumes (ITV and ETV). The cuff pressure of the endotracheal tube was measured by Mallinckrodt's aneroid pressure manometer. The anaesthesia machine, ventilator, equipments and drugs were checked beforehand. Intravenous access was secured and standard monitors were attached before induction. Patients were administered Midazolam 0.02 mg/kg IV and Fentanyl 1 mcg/kg IV after pre-oxygenation. Propofol 2 mg/kg IV was used in the induction of anaesthesia. Anaesthesia was deepened with 30% O_2 + 70% N_2O and 1-2% Sevoflurane on loss of verbal contact. After checking whether ventilation was possible with a face mask, the patient was given Rocuronium 0.6 mg/kg IV. Properly sized i-gel was selected based on the patient's weight as per the guidelines provided by the manufacturer. After inserting i-gel, the position was confirmed with observation of chest movements and $EtCO_2$ waveforms. If ventilation was inadequate, it was corrected by pulling or pushing of the device, chin lift, head extensions, and jaw thrust. The number of attempts to achieve proper placement was recorded. The number of failed attempts was also recorded. It was considered to be a failed attempt when the device had to be removed from the mouth before re-insertion. If there was a failure in re-insertion, it was taken as failed i-gel. Anaesthesia was maintained by administration of Propofol infusion at the rate of 6-12 mcg/kg/min and 30% O_2+ 70% N_2O.

Airway Leak Test:

The insertion of i-gel was followed by airway leak test. The fresh gas flow was kept at 3 L/min and the APL valve was closed. Care was taken not to allow airway pressure to go above 40 cm of H_2O. Two methods were used to measure the airway leak pressure.

Auscultation Method:

Observation of the airway pressure at which an audible gas leak occurred when the stethoscope was placed lateral to the thyroid cartilage.

Manometer Stability Method:

Observation of the airway pressure at which the aneroid manometer dial reached stability (i.e. the amount of gas leaked is proportionate to the fresh gas flow).

After the airway leak test, the patients were disconnected from anaesthesia machine and ventilated using the Servo i-Maquet ventilator for observation of ITV and ETV. Propofol infusion

was used to maintain anaesthesia. PCV at four inspiratory pressures (10, 15, 20 and 25cm of H_20) at a rate of 10 bpm and Inspiratory: Expiratory (I: E) ratio of 1:2 without Positive End Expiratory Pressure (PEEP) was used to ventilate the patients. ITV and ETV were noted. For each inspiratory pressure, the measurements were done for 10 breaths. I-gel was then removed and visible blood on the device noted. ETTs of suitable size were then used to intubate the patients. The cuff pressure was maintained at 27 cm of H_2O with the help of Mallinckrodt's aneroid pressure manometer. All the measurements done with i-gel were then repeated. The ETT was left in place after the measurements and used for ventilation during surgery.

Statistical Analysis:

For the purpose of sample size calculation, a difference in Leak Fraction (LF) of 0.20 and standard deviation of 0.15 were considered significant based on previous literature [16].The minimum required sample size calculated was 20 with a power of 80% and a significance level of 5%. However, we included 40 participants in our study. Distribution percentage of age, gender and ASA status in the study population were calculated. The Leak Volume (LV) as ITV-ETV and LF as LV/ITV were calculated. Computer software, Statistical Package for Social Sciences (SPSS) version 10 was used for statistical analysis. Student's t test was used to analyse the difference in LV and LF between the two groups. A two-tailed probability value of <0.05 was considered significant.

Results:

About 47% of study population fell in the age group of 40-59 years and about 37% patients in 20-39 years age group. Males constituted 67% of the study group. Sixty five percent of study population belonged to ASA grade I and thirty five percent belonged to ASA grade II.

In airway leak test with i-gel, the mean leak pressure was 25.03 ± 7.81 cm of H_2O with the manometer method and 24.71 ± 5.19 cm of H_2O with the auscultation method. There was no statistically significant difference between the values obtained from both the tests (P >0.05). In all the intubated patients, the airway pressure steadily reached 40 cm of H_2O. At an inspiratory pressure of 10 cm of H_2O, the mean LV was 12.76 ± 5.87 ml for i-gel and 10.88 ± 4.99 ml for the tube. The mean LF was 3.3 ± 0.80% for i-gel and 2.6 ± 0.70% for the tube. At 15 cm of H_2O, the mean LV for i-gel was 17.89 ± 9.54 ml and 14.98 ± 8.76 ml for the tube. The mean LF for i-gel was 5.6 ± 0.60% and 4.3 ± 0.40% for the tube. At 20 cm of H_2O, the mean LV for i-gel was 25.98 ± 8.29 ml and 20.23 ± 6.38 ml for the tube. The mean LF for i-gel was 7.2 ± 2.30% and 5.8 ± 2.70% for the tube. No statistically significant difference was found between these values of the two groups. At 25 cm of H_2O, the mean LV for i-gel was 58.08 ± 7.42 ml and 31.87 ± 6.15 ml for the tube (Fig.1). The mean difference was 26.21 ml which was found to be statistically significant (95% CI 23.96- 28.46; P< 0.01). The mean LF for i-gel was 9.6 ± 3.80% and 7.1 ± 2.90% for the tube (Fig.2). The mean difference was 2.5% which was found to be statistically significant (95% CI 1.76-3.24; P<0.001).

Secondary results were 1) Insertion of i-gel was possible in all the patients in the first attempt. 2) Manipulations were done only in five out of forty patients (12%) after insertion. 3) More than one manipulation was not needed in any of the cases. 4) Four i-gels (10%) showed visible blood after removal.

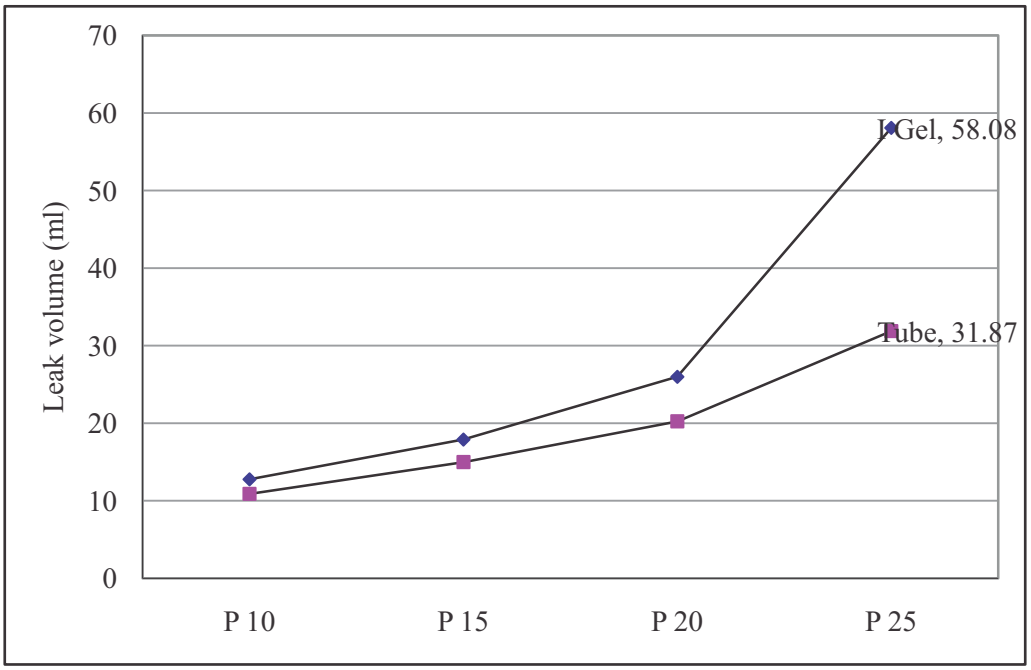

Fig. 1: Leak Volume (ml) for I-gel and ETT at Different Inspiratory Pressures (cm of H_20)

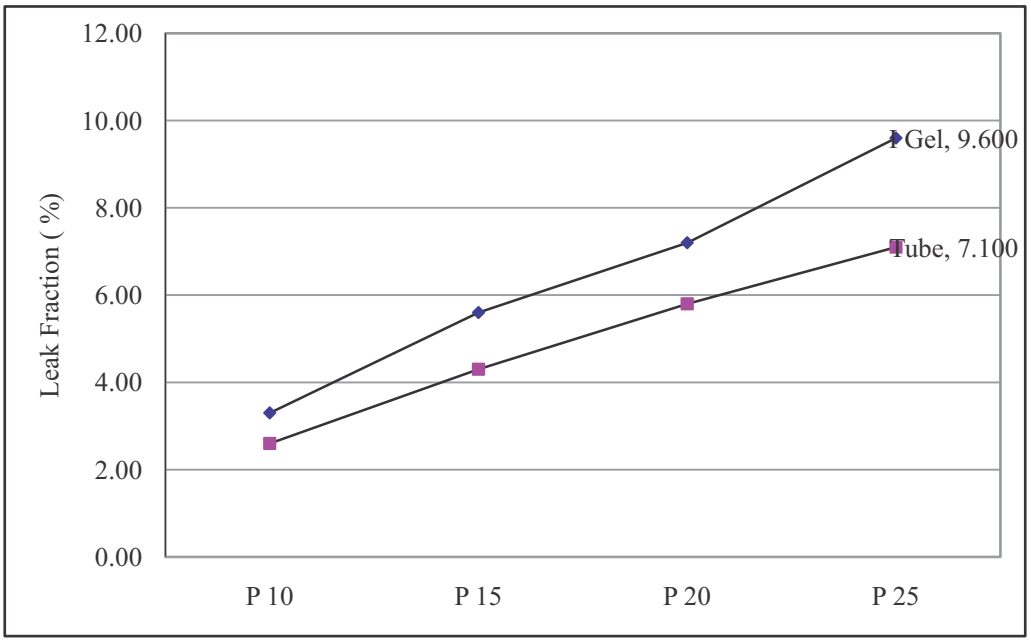

Fig. 2: Leak Fraction (%) for I-gel and ETT at Different Inspiratory Pressures (cm of H_20)

Discussion:

Endotracheal intubation remains the gold standard for ventilation during anaesthesia. But SADs have been replacing ETTs in many scenarios [1-4]. This is because of several advantages that SADs have over endotracheal intubation like less trauma to airway [1, 11-14] less stress response during intubation and extubation [17-19], lower incidence of sore throat [11, 20] and ease of insertion [7-8]. I-gel is dissimilar from other SADs in that it has a non-inflatable cuff and thus reduces airway morbidity further [1, 11-14]. But absence of inflatable cuff can theoretically cause significant gas leaks during ventilation. So we compared gas leaks of i-gel with that of ETT, since it is the gold standard. There is evidence in literature suggesting that PCV is better than VCV for controlled ventilation using SADs [15-16]. The amount of leak is dependent on the pressure created between the supraglottic tissues and the airway device [16]. So we used PCV in our study for ventilation.

Airway leak pressures were studied using auscultation and manometer methods and the values obtained by these methods were similar which is supported by previous studies as well [21-24]. In our study, no significant statistical difference was noted between the LV and LF in i-gel group and ETT group at 10,15 and 20 cm of H_2O. However, at 25 cm of H_2O, there was a significant statistical difference in LV and LF between the two devices which is corroborated by a study by Uppal *et al*. in 2009 [16]. But a similar study done in 2017 by Ankur *et al.* showed significant leak at 20 cm of H_2O with i-gel [24]. We had no cases of failed insertion. Only five out of forty (12%) cases needed manipulation after insertion. This observation that i-gel is easy to insert has been supported by several other studies [7-8]. On removing the i-gel, visible blood was found on four of them (10%). Literature shows incidence of blood on SADs on removal to be 4 - 13% [1, 16, 25-26].

One limitation with our study is that i-gel was tested for only PCV and not VCV. Another limitation is that the efficacy of i-gel with inspiratory pressures greater than 25 cm of H_2O which can be associated with many surgeries were not studied.

Conclusion:

Through this study, we encourage and support the use of i-gel for PCV, presuming that the inspiratory pressures are adjusted to the limit of 25 cm of H_2O. This study is also supportive of the fact that i-gels are SADs that are easy to insert without significant trauma to the airway.

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