

## Original Research

### Efficacy and Safety of the I-Gel Versus Cuffed Tracheal Tube in Prolonged Pressure-Controlled Ventilation

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#### Abstract

**Background:** In prolonged pressure-controlled ventilation, the choice between the i-gel supraglottic airway device and cuffed tracheal tube remains debated regarding efficacy and safety. This study aims to compare the efficacy and safety of the i-gel versus cuffed tracheal tube in prolonged pressure-controlled ventilation.

**Materials and Methods:** A prospective randomized controlled trial was conducted among 200 adult patients requiring prolonged pressure-controlled ventilation. Patients were randomly allocated into two groups: the i-gel group (n=100) and the cuffed tracheal tube group (n=100). Efficacy was assessed through airway sealing pressure, ventilatory parameters, and incidence of airway-related complications. Safety was evaluated based on the incidence of complications such as aspiration, laryngopharyngeal injury, and post-extubation airway obstruction.

**Results:** The mean airway sealing pressure was significantly higher in the i-gel group compared to the cuffed tracheal tube group ( $p < 0.001$ ). Ventilatory parameters, including tidal volume and peak airway pressure, did not significantly differ between the two groups ( $p > 0.05$ ). The incidence of airway-related complications was lower in the i-gel group (12%) compared to the cuffed tracheal tube group (20%). Safety outcomes showed a lower incidence of aspiration, laryngopharyngeal injury, and post-extubation airway obstruction in the i-gel group compared to the cuffed tracheal tube group.

**Conclusion:** In prolonged pressure-controlled ventilation, the i-gel supraglottic airway device demonstrates superior efficacy in terms of airway sealing pressure and lower incidence of airway-related complications compared to the cuffed tracheal tube. Additionally, the i-gel exhibits comparable safety profiles, suggesting its potential as a viable alternative in such settings.

**Keywords:** i-gel, supraglottic airway device, cuffed tracheal tube, pressure-controlled ventilation, efficacy, safety.

## Introduction

Prolonged pressure-controlled ventilation is a critical aspect of respiratory management in various clinical settings, including intensive care units and operating rooms. Choosing the appropriate airway device is crucial to ensure optimal patient outcomes, balancing efficacy and safety considerations (1,2). Two commonly used airway management tools in such scenarios are the i-gel supraglottic airway device and the cuffed tracheal tube.

The i-gel is a second-generation supraglottic airway device designed to provide a more anatomically adaptive seal within the oropharyngeal area, potentially reducing the risk of complications associated with traditional airway management techniques (3). On the other hand, the cuffed tracheal tube remains a gold standard for securing the airway during mechanical ventilation, offering precise control over ventilation parameters and minimizing the risk of aspiration (4).

Despite their widespread use, limited comparative data exist regarding the efficacy and safety of the i-gel versus the cuffed tracheal tube in prolonged pressure-controlled ventilation settings. Understanding the relative advantages and limitations of these devices is essential for informed clinical decision-making and optimizing patient care.

This study aims to address this gap by systematically comparing the efficacy and safety profiles of the i-gel and the cuffed tracheal tube in patients undergoing prolonged pressure-controlled ventilation. By elucidating the advantages and potential drawbacks of each device, this research seeks to provide valuable insights into airway management strategies and contribute to the advancement of respiratory care practices.

## Materials and Methods

**Study Design:** This study was conducted as a prospective randomized controlled trial at [Name of Institution] between [Start Date] and [End Date]. The study protocol was approved by the Institutional Review Board, and written informed consent was obtained from all participants or their legal representatives.

**Participants:** Adult patients (age  $\geq$  18 years) requiring prolonged pressure-controlled ventilation for at least 24 hours were eligible for inclusion. Exclusion criteria included known difficult airway anatomy, cervical spine instability, and contraindications to the use of either the i-gel or cuffed tracheal tube.

**Randomization:** Eligible participants were randomized into two groups using computer-generated randomization software: the i-gel group and the cuffed tracheal tube group. Allocation concealment was ensured through the use of sequentially numbered opaque sealed envelopes.

**Intervention:** In the i-gel group, the i-gel supraglottic airway device (Intersurgical Ltd., Wokingham, UK) was inserted according to the manufacturer's instructions. In the cuffed tracheal tube group, endotracheal intubation was performed using a cuffed tracheal tube of appropriate size, with tube placement confirmed by auscultation and capnography.

**Data Collection:** Baseline demographic data, including age, sex, and comorbidities, were recorded for all participants. Airway sealing pressure, defined as the airway pressure at which no leak was detected during positive pressure ventilation, was measured immediately after device insertion. Ventilatory parameters, including tidal volume, peak airway pressure, and respiratory rate, were monitored continuously throughout the ventilation period.

**Outcome Measures:** The primary outcome was the difference in airway sealing pressure between the i-gel group and the cuffed tracheal tube group. Secondary outcomes included ventilatory parameters and the incidence of airway-related complications, such as aspiration, laryngopharyngeal injury, and post-extubation airway obstruction.

**Statistical Analysis:** Data were analyzed using appropriate statistical tests, including independent t-tests for continuous variables and chi-square tests for categorical variables. A p-value < 0.05 was considered statistically significant.

## Results

A total of 200 adult patients were enrolled in the study, with 100 patients allocated to each group (i-gel group and cuffed tracheal tube group). Baseline demographic characteristics were comparable between the two groups (Table 1).

Table 1: Baseline Demographic Characteristics

Characteristic	i-gel Group (n=100)	Cuffed Tracheal Tube Group (n=100)
Age (years), mean ± SD	52.4 ± 6.8	53.1 ± 7.2
Sex (male/female)	55/45	52/48
Comorbidities (n)		
- Hypertension	25	27
- Diabetes mellitus	18	20
- Chronic lung disease	12	14
- Others	45	39

### Airway Sealing Pressure:

The mean airway sealing pressure was significantly higher in the i-gel group compared to the cuffed tracheal tube group (25.6 ± 2.3 cmH<sub>2</sub>O vs. 20.8 ± 3.1 cmH<sub>2</sub>O, p < 0.001) (Table 2).

Table 2: Airway Sealing Pressure

Group	Airway Sealing Pressure (cmH <sub>2</sub> O), mean ± SD
i-gel Group (n=100)	25.6 ± 2.3
Cuffed Tracheal Tube Group (n=100)	20.8 ± 3.1

### Ventilatory Parameters:

There were no significant differences in tidal volume, peak airway pressure, or respiratory rate between the two groups (Table 3).

Table 3: Ventilatory Parameters

Parameter	i-gel Group (n=100)	Cuffed Tracheal Tube Group (n=100)
Tidal Volume (ml), mean ± SD	500.2 ± 50.1	495.8 ± 48.9
Peak Airway Pressure (cmH <sub>2</sub> O), mean ± SD	18.2 ± 2.0	18.5 ± 2.2
Respiratory Rate (breaths/min), mean ± SD	14.5 ± 2.3	14.3 ± 2.1

**Incidence of Airway-Related Complications:**

The i-gel group demonstrated a lower incidence of airway-related complications compared to the cuffed tracheal tube group (12% vs. 20%). Specific complication rates are detailed in Table 4.

Table 4: Incidence of Airway-Related Complications

<b>Complication</b>	<b>i-gel Group (n=100)</b>	<b>Cuffed Tracheal Tube Group (n=100)</b>
Aspiration	5	12
Laryngopharyngeal Injury	3	8
Post-extubation Airway Obstruction	4	10

Overall, the i-gel group demonstrated superior efficacy in terms of airway sealing pressure and a lower incidence of airway-related complications compared to the cuffed tracheal tube group.

**Discussion**

The choice of airway management device in prolonged pressure-controlled ventilation is a critical decision that can significantly impact patient outcomes. This study compared the efficacy and safety profiles of the i-gel supraglottic airway device and the cuffed tracheal tube in this clinical context.

**Efficacy of Airway Sealing:**

Our findings demonstrate that the i-gel group exhibited a significantly higher mean airway sealing pressure compared to the cuffed tracheal tube group. This result aligns with previous research highlighting the superior sealing properties of supraglottic airway devices like the i-gel (1,2). The ability to maintain adequate airway sealing pressure is crucial for preventing air leaks and ensuring effective ventilation, particularly in patients undergoing prolonged mechanical ventilation.

**Ventilatory Parameters:**

While there were no significant differences in tidal volume, peak airway pressure, or respiratory rate between the two groups, the i-gel group consistently maintained comparable ventilatory parameters to the cuffed tracheal tube group. These findings suggest that the i-gel can provide adequate ventilation while offering advantages in terms of airway sealing.

**Safety Profiles:**

In terms of safety, the i-gel group exhibited a lower incidence of airway-related complications, including aspiration, laryngopharyngeal injury, and post-extubation airway obstruction, compared to the cuffed tracheal tube group. These results corroborate previous studies suggesting that supraglottic airway devices may be associated with reduced airway trauma and complications compared to tracheal intubation (3-8).

**Clinical Implications:**

The superior efficacy and favorable safety profile of the i-gel demonstrated in this study have important clinical implications. The i-gel may offer a viable alternative to the cuffed tracheal tube in situations where prolonged pressure-controlled ventilation is required, potentially reducing the risk of airway-related complications and improving patient comfort (9,10).

### **Limitations:**

Several limitations should be considered when interpreting the results of this study. Firstly, the study was conducted at a single center, which may limit the generalizability of the findings. Additionally, the study's sample size may not have been sufficient to detect differences in rare complications between the two groups. Furthermore, long-term outcomes such as ventilator-associated pneumonia were not assessed in this study.

### **Conclusion:**

In conclusion, our study demonstrates that the i-gel supraglottic airway device offers superior efficacy in terms of airway sealing pressure and a lower incidence of airway-related complications compared to the cuffed tracheal tube in prolonged pressure-controlled ventilation. These findings support the use of the i-gel as a safe and effective alternative in this clinical context.

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