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Original Article / Özgün Araştırma

Clinical Comparison of I-Gel Supraglottic Airway Device and Cuffed Endotracheal Tube for Pressure-Controlled Ventilation During Routine Surgical Procedures

Rutin Cerrahi İşlemlerde I-Gel Supraglottik Havayolu Aracı ile Kaflı Endotrakeal Tüp Kullanımının Basınç Kontrollü Ventilasyon Açısından Klinik Karşılaştırması

Ankur Dhanda[1], Shalendra Singh[1], Anju R. Bhalotra[2], Siddharth Chavali[1]

[1]*Department of Neuroanaesthesiology and Critical Care, All India Institute of Medical Science, Delhi, India*

[2]*Department of Anaesthesiology and Critical Care, Maulana Azad Medical College, Delhi, India*

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Abstract / Öz

Objective: Recently, there has been a trend favouring the use of supraglottic airway devices over endotracheal tubes (ETT) during short surgical procedures. In this study, we are going to assess the suitability of one such supraglottic airway device, i-gel, for pressure-controlled ventilation (PCV) during routine surgical procedures.

Methods: The airway management for 60 patients was done with either i-gel (Group I) or cuffed tracheal tube (Group E) for this prospective, randomised, double-blinded study. Insertion time, number of attempts, ease of insertion and haemodynamic monitoring were recorded before, during and after insertion of these devices. Airway leak tests, leak volume and leak fraction were measured at 15, 20 and 25 cm H_2O PCV, and pharyngolaryngeal morbidity was evaluated postoperatively.

Results: I-gel is easier to insert than a tracheal tube (p=0.0056). The increase in heart rate and MAP was higher following insertion of tracheal tube in the first few minutes (p<0.001) and subsequently became comparable between the two groups. The leak volume and leak fraction between the two groups were comparable at 15 cm H_2O PCV, but significant difference was seen at 20 and 25 H_2O PCV between the two groups (p=0.232, p<0.001, p<0.001). Thirty minutes later, the leak volume and leak fraction between groups were comparable at 15 cm H_2O PCV (p=0.495, p=0.104) but not at 20 and 25 H_2O PCV (p<0.001, p<0.001). Pharyngolaryngeal morbidity was significantly lesser in the i-gel group.

Conclusion: I-gel provides a reasonable alternative to cuffed ETT for pressure-controlled ventilation provided the pressures can be limited to 15 to 20 cm H_2O.

Keywords: I-gel, pressure-controlled ventilation, supraglottic airway devices

Amaç: Son zamanlarda kısa cerrahi işlemlerde supraglottik havayolu araçlarının endotrakeal tüplere (ETT) göre daha çok kullanımı yönünde bir eğilim vardır. Bu çalışmada, rutin cerrahi işlemlerde supraglottik bir havayolu aracı olan i-gel kullanımının basınç kontrollü ventilasyon (PCV) açısından uygunluğu değerlendirilmektedir.

Yöntemler: Bu prospektif randomize ve çift-kör çalışma için, 60 hastada havayolu yönetimi I-gel (Grup I) veya kaflı trakeal tüp (Grup E) ile yapıldı. Bu cihazların yerleştirilmesinden önce, yerleştirilmesi sırasında ve yerleştirilmesinden sonra hastalar yerleştirme zamanı, deneme sayısı, yerleştirme kolaylığı ve hemodinamik parametreler açısından değerlendirildi. Havayolu kaçak testleri, kaçak hacmi ve kaçak fraksiyonu 15, 20 ve 25 cm H_2O PCV'de ölçüldü ve faringolaringeal morbidite postoperatif olarak değerlendirildi.

Bulgular: I-gel'in yerleştirilmesinin trakeal tüpe kıyasla daha kolay olduğu görüldü (p=0,0056). Trakeal tüpün yerleştirilmesinin ardından ilk dakikalarda, kalp atım hızı ve ortalama arteryel basınçtaki artış oranının daha yüksek olduğu izlendi (p<0,001) ve sonrasında iki grup arasında benzer seviyeye geldi. Kaçak hacmi ve kaçak fraksiyonu 15 cm H_2O PCV'de her iki grupta benzerdi, ancak 20 ve 25 H_2O PCV'de anlamlı farklılık gözlendi (p=0,232, p<0,001, p<0,001). Otuz dakika sonra, gruplar arasındaki kaçak hacmi ve kaçak fraksiyonu değerleri 15 cm H_2O PCV'de (p=0,495, p=0,104) benzer iken, 20 ve 25 H_2O PCV'de (p<0,001, p<0,001) değildi. Faringolaringeal morbidite oranı I-gel grubunda anlamlı ölçüde daha düşük bulundu.

Sonuç: I-gel supraglottik havayolu aracı, basınç değerleri 15 ile 20 cm H_2O arasında olduğu takdirde, kaflı ETT'ye karşı makul bir alternatif olmaktadır.

Anahtar Sözcükler: I-gel, basınç kontrollü ventilasyon, supraglottik havayolu araçları

Introduction

Endotracheal tube (ETT) is the proven standard-of-care for airway management in adults undergoing general anaesthesia (GA). However, supraglottic airway devices (SAD) may offer distinct advantages over the ETT in terms of increased speed and reliability of placement, maintaining haemodynamic stability during induction and emergence (1, 2), better oxygenation during emergence (3) and increased patient satisfaction by decreasing the incidence of postoperative sore throat (POST) (4, 5) and voice alteration.

Address for Correspondence/Yazışma Adresi: Shalendra Singh E-mail: drsinghafmc@gmail.com

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The i-gel™ (Intersurgical, Berkshire, Wokingham, UK) (6) is a novel SAD designed for use during GA. I-gel design obviates the need for cuff inflation, has a reduced chance of axial rotation and thus malpositioning and reduced the chances of kinking as compared to ETT. The insertion of i-gel has also been found to be significantly easier and faster compared with other SAD (7, 8).

The decelerating flows of pressure-controlled ventilation (PCV) mode have been shown to decrease the peak airway pressure (P_{peak}), higher instantaneous flow peaks and may allow better alveolar recruitment, minimise pressure-related leaks and gastric insufflation and hence may provide more effective ventilation than other modes (9-13).

There is a paucity of studies comparing i-gel with cuffed ETT as a ventilatory device during PCV. Thus, our study was designed to assess i-gel as a suitable SAD for PCV during GA for routine surgical procedures.

Methods

After obtaining Institutional Ethics Committee approval and written informed consent, 60 patients age between 18 and 65 years, ASA grade I or II, body mass index (BMI) between 18 and 30 kg/m^2, for various elective surgical procedures with anticipated duration not exceeding 2 h were enrolled for this prospective, randomised, double-blinded study. Patients with presence of any significant acute or chronic lung disease, inadequate cervical mobility/cervical malformation, with known/predicted difficult airway/reduced mouth opening/disease of oral cavity, full stomach/increased risk of aspiration (GERD, hiatus hernia, diabetes mellitus), pregnancy, surgery of the head and neck procedures not performed in supine position and laparoscopic surgeries were excluded from the study.

After computer-generated randomisation, patients were assigned in either Group I or E in which airway management was done with i-gel or with cuffed ETT. I-gel size 3 for 30–60 kg; 4 for 50–90 kg and a size 5 was used for >90 kg weight. ETT size 8.5 mm ID for male and 7.5 for female participants was used. The patients were pre-medicated with intravenous fentanyl 2 μg kg^{-1}, and anaesthesia was induced with propofol 1.5-2 mg kg^{-1} and muscle relaxation achieved with rocuronium 0.6 mg kg^{-1} and confirmed using a train-of-four stimulation count (TOF=0). The cuff of the ETT was inflated to a pressure of 25 cm H_2O using a handheld aneroid pressure gauge and placement confirmed by capnography and by chest auscultation.

Insertion time was recorded as time from insertion of i-gel into the mouth or insertion of laryngoscope blade into the mouth to appearance of the first capnographic square waveform. Each 'attempt' would be defined as re-insertion of the airway device into the mouth and the respective times would be T1, T2 and T3. Effective airway time would have been calculated by adding T1, T2 and T3. We defined 'insertion failure' of the device as one comprising more than three unsuccessful attempts in which case the airway would have been secured at the discretion of the senior anaesthesiologist supervising the case. The ease of insertion of the airway device was subjectively assessed on a 5-point scale (1=easy, 2=not so easy, 3=difficult, 4=very difficult, 5=impossible). In Group I, an appropriate-sized nasogastric tube (size 14 Fr for size 5 i-gel and 12 Fr for sizes 3 and 4 i-gel) was inserted through the gastric drain channel after lubrication. Ease of insertion of the gastric tube was assessed on a 3-point scale (1=easy, 2=difficult, 3=impossible). Confirmation of proper placement of the gastric catheter was by detection of injected air by auscultation over the epigastrium and by aspiration of gastric contents. In both the groups, heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2) and end tidal carbon dioxide ($EtCO_2$) were recorded before induction (baseline), before device insertion (T0), every minute for the first 5 min after insertion of the airway device (T1, T2, T3, T4, T5) and henceforth, every 5 min for the entire duration of the surgery.

Airway leak tests were then performed in Group I. The fresh gas flow was adjusted to 3 L min^{-1}, and the adjustable pressure limiting valve of the circle system was completely closed. Airway pressures were not allowed to exceed 40 cm H_2O.

Test 1 (Auscultation): Measured the minimal airway pressure at which an audible gas leak occurred by using a stethoscope placed just lateral to thyroid cartilage.

Test 2 (Manometer stability): Observation of the aneroid manometer dial as the pressure from the breathing system increased and noted the airway pressure at which the dial reached stability (i.e. the airway pressure at which leak is in equilibrium with fresh gas flow).

Anaesthesia was maintained with O_2 and N_2O in isoflurane (1%–1.5%). Once a clear airway was established, the lungs were ventilated at three different pressures (15, 20, 25 cm H_2O) using PCV at a rate of 10 breaths min^{-1} and an I:E ratio of 1:2 with no PEEP. Inspired tidal volumes (TV) and expired TV were recorded, and the leak volume (LV=ITV –ETV) was calculated. The leak fraction (LF) was calculated as LV divided by ITV (i.e. LF=LV/ITV). Measurements were taken over 10 breaths for each pressure setting.

Gastric insufflation was assessed by auscultation over the patient's epigastric area. PCV was then maintained at the pressure (15, 20, 25 cm H_2O) which was lower than the leak pressure of the device in group I and at 20 cm H_2O in Group E at a rate adapted to maintain $EtCO_2$ in the range of 30–35 mm Hg. Thirty minutes later, once again, the LF was estimated with pressures of 15, 20 and 25 cm H_2O and measurements were taken over 10 breaths for each pressure setting.

At the end of the surgery, any blood staining on the laryngoscope, the tracheal tube, or i-gel was documented. Complica-

tions during insertion, maintenance and removal were noted for each patient. Pharyngolaryngeal morbidity was evaluated in the recovery room and 24 h postoperatively.

The primary endpoint of our study was the difference in the LF between the two airway devices under investigation. Secondary outcomes included differences in the LV, airway leak pressures, success of first attempt insertion, number of manipulations after or during insertion, haemodynamic response to device insertion and any complications.

Statistical analysis

The sample size was calculated to be 30 in each group with an α error of 0.05 and power of 90% considering a difference in the LF of more than 16% to be significant. Quantitative data (LF, LV, airway leak pressures and time of insertion) were analysed using unpaired t test. Qualitative data (ease of insertion, success rate first attempt insertion, number of insertion attempts and any complications) were compared using χ^2 test.

Results

The patients' demographic profile including age, sex, height, weight, BMI and ASA physical status were comparable in both the groups (Table 1). The airway examination including interdental distance, thyromental distance, Modified Mallampati classification and neck circumference were comparable in both the groups (Table 1).

I-gel is easier (easy in 96.67% and not so easy in 3.33% patients) to insert as compared to an ETT (easy in 73.33%, not so easy in 20% and difficult in 6.67% patients) (p=0.0056). The mean time for insertion of device in group I and E was found to be 10.03±2.01 and 16.67±2.87 seconds (p<0.001). In both the groups, airway devices were successfully placed in the first attempt. Two patients in Group I required jaw thrust, whereas five patients in Group E required external laryngeal manoeuvres with no trauma/adverse events at insertion. In group I, gastric tube was successfully placed in all the patients. Insertion of the gastric tube was easy in 27 patients (90%) and difficult in three patients (10%).

Between the two groups, HR was comparable at baseline and decreased slightly before device insertion. However, the increase in HR was higher following insertion of ETT in the first three minutes (p<0.001) and then became comparable at T4 and T5 between the two groups (Table 2 and Figure 1). Also, the increase in MAP values was higher in Group E in first four minutes after insertion (p<0.001) and became insignificant at the fifth minute after device insertion (Table 2 and Figure 1).

In Group I, leak test 1 and 2 showed a mean airway leak pressure of 27.13±2.50 and 27.33±2.48 cm H_2O (p=0.083). Airway leak pressures for all the intubated patients consistently reached above 35 cm H_2O. The LV and LF between group was comparable at 15 cm H_2O PCV but a significant difference was seen at 20 and 25 cm H_2O PCV between the two groups (p=0.232, p<0.001, p<0.001) (Table 3).

Table 1. Clinical patients' characteristics and airway parameters in both the groups

	I-gel		ETT		p
Age (years) Mean±SD	28.57±5.19		30.93±7.45		0.079
Gender					
Male	16 (53.33%)		17 (56.67%)		
Female	14 (46.67%)		13 (43.33%)		0.397
Height (cm) Mean±SD	165.03±6.99		163.7±9.6		0.270
Weight (kg) Mean±SD	62.17±9.02		59.47±10.68		0.147
BMI (kg/m^2) Mean±SD	22.48±2.48		21.96±1.99		0.186
ASA Grade					
I	23		26		
II	7		4		0.158
Interdental distance (cm) Mean±SD	5.41±0.34		5.30±0.40		0.127
Thyromental distance (cm) Mean±SD	6.88±0.17		6.92±0.32		0.270
Neck circumference (cm) Mean±SD	33.97±2.37		34.07±2.79		0.440
Modified Mallampati Classification					
I	13	43.33%	18	60%	0.098
II	17	56.67%	12	40%	

SD: standard deviation; ETT: endotracheal tube; BMI: body mass index; ASA: American Society of Anaesthesiology

Table 2. Heart rate and mean arterial pressure response to device insertion

	Heart rate (beats min-1) [mean±SD]			Mean arterial pressure (mm Hg) [mean±SD]		
Time	**I-gel**	**ETT**	**p**	**ETT**	**I-gel**	**p**
Baseline	78.27±7.55	76.50±6.60	0.169	89.17±5.00	86.70±7.53	0.070
T0	76.67±7.41	75.03±6.63	0.185	83.60±5.80	82.43±6.70	0.237
T1	81.27±7.82	92.40±8.43	<0.001	103.53±4.82	87.40±7.78	<0.001
T2	80.60±7.58	91.10±7.27	<0.001	102.90±4.54	87.20±7.58	<0.001
T3	80.57±7.86	85.87±6.96	0.003	96.03±4.30	87.50±7.08	<0.001
T4	80.00±7.64	81.23±6.05	0.245	92.07±4.80	87.03±6.84	<0.001
T5	79.43±7.38	79.20±7.19	0.450	88.87±4.21	86.90±6.96	0.095

T0=Before device insertion, T1–T5 =1–5 min after device insertion

Table 3. Leak volume, Leak fractions after insertion of ETT and i-gel and after 30 min of insertion at 15, 20 and 25 cm H_2O PCV and Comparing Leak volume and Leak Fraction at 15, 20 and 25 cm H_2O PCV for both the groups

		PCV 15 cm H_2O	**PCV 20 cm H_2O**	**PCV 25 cm H_2O**
LV (mL)	ETT	12.81±8.44	19.71±9.65	25.85±12.01
	I-gel	12.33±7.44	25.10±10.83	38.82±12.52
	p	0.232	<0.001	<0.001
LF	ETT	0.026±0.016	0.029±0.014	0.029±0.022
	I-gel	0.029±0.025	0.036±0.016	0.043±0.017
	p	0.232	<0.001	<0.001
LV (mL) 30 min later	ETT	12.31±7.97	19.64±9.68	25.82±12.02
	I-gel	12.30±7.39	25.47±5.96	38.57±10.71
	p	0.495	<0.001	<0.001
LF 30 min later	ETT	0.025±0.016	0.029±0.014	0.028±0.014
	I-gel	0.027±0.016	0.035±0.010	0.042±0.015
	p	0.104	<0.001	<0.001
Comparing LV for Group I	Initially	12.33±7.44	25.10±10.83	38.82±12.52
	30 min later	12.30±7.39	25.47±5.96	38.57±10.71
	p	0.477	0.289	0.396
Comparing LF for Group I	Initially	0.029±0.025	0.036±0.016	0.043±0.017
	30 min later	0.027±0.016	0.036±0.010	0.042±0.015
	p	0.152	0.408	0.432

LV: leak volume; LF: leak fractions; ETT: endotracheal tube; PCV: pressure control ventilation

In two patients, the airway seal pressures were found to be 20 and 22 cm H_2O for the i-gel. In these two patients, PCV at 25 cm H_2O was not attempted. Thirty minutes later, the LV and LF between group was comparable at 15 cm H_2O PCV (p=0.495, p=0.104) but significant difference was seen at 20 and 25 cm H_2O PCV between the two groups (p<0.001, p<0.001) (Table 3, Figures 2 and 3). However, LF for ventilation with i-gel increased with increasing airway pressures whereas LF with the ETT remained unchanged.

Adequate TV was delivered with PCV at 15 cm H_2O in all patients with maintenance of normocapnia and oxygenation. Also, at higher pressures of 20 and 25 cm H_2O, there was no clinical evidence of substantial leak evidenced by gastric insufflations or inadequate ventilation. The small difference

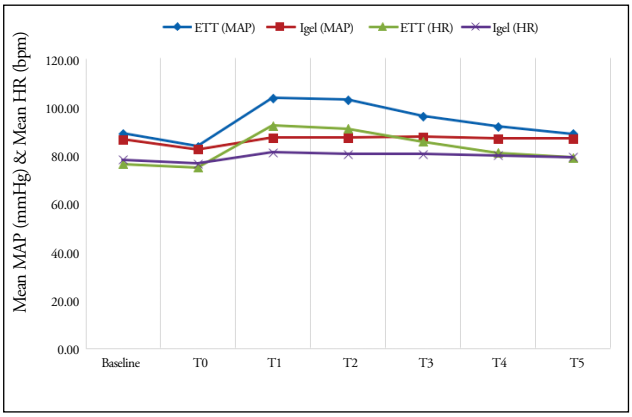

Figure 1. Heart rate and mean arterial pressure response to device insertion
ETT: endotracheal tube; HR: heart rate; MAP: mean arterial pressure; T0: Before device insertion; T1–T5: 1–5 min after device insertion

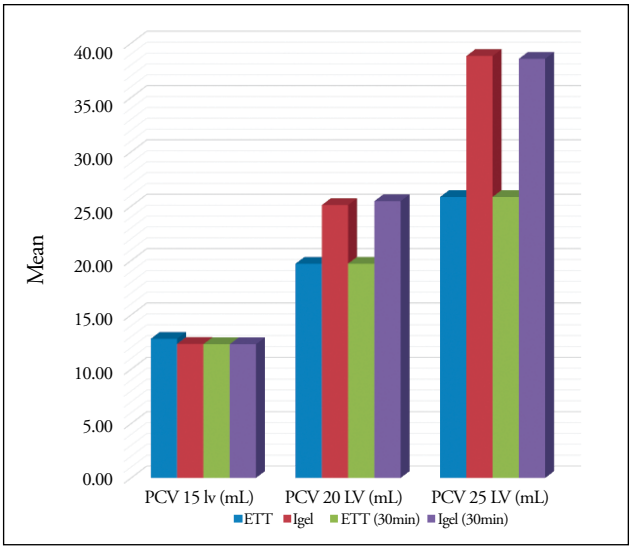

Figure 2. Leak volume after insertion of ETT and i-gel and after 30 min of insertion at 15, 20 and 25 cm H_2O for both the groups
ETT: endotracheal tube; PCV: pressure control ventilation

of LVs and fractions at higher pressures, although statistically significant is unlikely to be of any clinical importance.

There were no complications of pharyngolaryngeal morbidity as defined during insertion, maintenance and removal of the device in either group. Blood on removal of device was seen on two i-gel's (6.67%), which could be attributed to slight trauma to the oropharyngeal mucosa occurring at the time of placement of the device (p=0.075). Seven patients (23.33%) in Group E but no patient in Group I complained of hoarseness of voice in the immediate postoperative period (p=0.002). In one patient, the hoarseness persisted up to 24 h postoperatively (p=0.15). One patient (3.33%) in Group I and no patient in Group E had dysphagia in the immediate postoperative period (p=0.15). No patient complained dysphagia after 24 h postoperatively in either group. Eight patients in Group E (26.67%) and two patients in Group

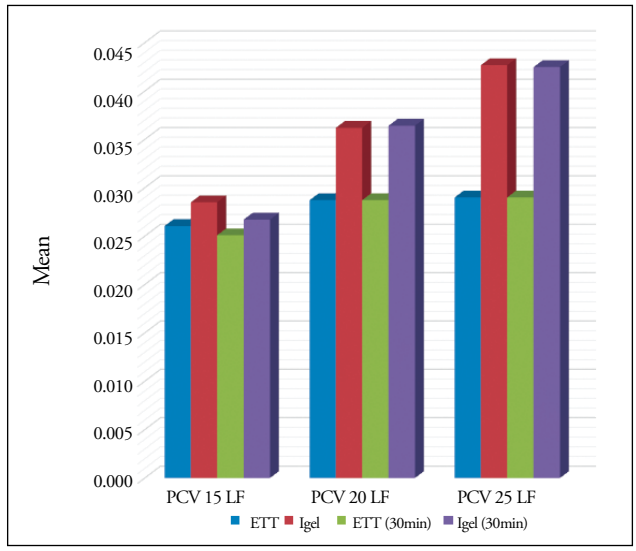

Figure 3. LFs after insertion of ETT and i-gel and after 30 min of insertion at 15, 20 and 25 cm H_2O for both the groups
ETT: endotracheal tube; PCV: pressure control ventilation

I (6.67%) complained of sore throat in the immediate postoperative period (p=0.018). No patient complained of sore throat 24 h later (Table 4).

Discussion

Recently, there has been a trend towards substituting an SAD for a tracheal tube for controlled ventilation in patients with a minimal risk of aspiration.

The i-gel has been studied and shown to have high insertion success rate and low device failures under both spontaneous and controlled ventilation (7, 14-17). Various studies have reported a median insertion time for the i-gel ranging from 5 to 15 sec (14, 16, 18).

The haemodynamic response to insertion of i-gel was significantly less than that for endotracheal intubation (2, 19) and is a reflection of an increase in sympathoadrenal activity due to oropharyngeal and laryngotracheal stimulation (20). I-gel has a soft gel thermoplastic elastomer cuff and may prevent stress stimulation. All the haemodynamic parameters returned to near-baseline values within 5 min of device insertion in our study. Previous study also concluded that the NIBP, HR, plasma epinephrine, norepinephrine and vasopressin concentrations increased slightly in response to laryngoscopy and intubation, all returning to or below baseline 5 min later (21).

The mean airway seal pressure varies to be 24 to 30 cm H_2O (14-17, 22) for i-gel using the auscultation method and manometer stabilisation method. Among tests available for assessing sealing pressure, manometer stability test had better interobserver reliability and may be more appropriate (23), and studies have found no difference between values obtained by manometer stability and auscultation method (22).

Table 4. Pharyngolaryngeal morbidity immediate post operatively and 24 h later

	ETT	I-gel	p
Blood on removal of device	0	2 (6.67%)	0.075
Hoarseness immediate post op	7 (23.33%)	0	0.002
Hoarseness 24 h post op	1 (3.33%)	0	0.15
Dysphagia immediate post op	0	1 (3.33%)	0.15
Dysphagia 24 h post op	0	0	
Sore throat immediate post op	8 (26.67%)	2 (6.67%)	0.018
Sore throat 24 h post op	0	0	

ETT: endotracheal tube

During PCV, the LV is affected by the pressure generated by the airway device against the supraglottic tissues and has been found to be a more efficient and safer mode than volume-controlled ventilation for controlled ventilation with a SAD (9-13).

We found slight decrease in the LV and LF 30 min later in Group I. Probably, the seal with the i-gel did not seem to improve much over time in our study. One of the possible reasons could be re-using of the i-gel in our study. It is found that ventilation with the SAD was adequate at all ventilation pressures and comparable with tracheal tube ventilation (24). Our study found similar LFs for ETT at different pressures. No significant difference was found between the LFs of the i-gel and the tracheal tube measuring the gas leaks with i-gel and comparing these values with that of the ETT (22). They suggested that the i-gel can be used as a reasonable alternative to the tracheal tube during PCV with moderate airway pressures. The LFs and LVs at 20 and 25 cm H_2O PCV were comparable with those found in our study.

Pharyngolaryngeal morbidity findings are similar to those reported with other SADs. The incidence of visible blood with the use of other SADs has been quoted from 12% to 18%, depending upon the type of SAD, the technique of insertion and ease of insertion (25). Airway management had the strongest influence on the incidence of pharyngolaryngeal morbidity. Literature (4, 5, 26) conclude that use of i-gel has shown clinically fewer postoperative sore throat (6%-12%), dysphagia (4%-17.5%), hoarseness (4%-12%) compared to ETT having sore throat (22%-45%), dysphagia (2%-11%) and dysphonia (4%). The low morbidity rate in our study is of note and could have been due to the high first attempt success rate and the tensile properties of the non-inflatable cuff resulting in a lower pressure being exerted against the pharyngeal structures.

Our study had some limitations. First, it was not a cross-over study so we could not limit the influence of interpatient variability during the comparison. Second, we were re-using i-gels due to financial constraints. In addition, we did not assess the sealing pressure after 30 min. It could have perhaps added important information, as reports have emerged that the seal of the i-gel seems to improve over time due to the thermoplastic cuff's warming to body temperature (6, 7). It was also impossible to blind the airway operator to the device used, hence leading to a potential for bias. We only studied non-obese patients with normal airways, and the results cannot directly be extrapolated to other types of patients. Therefore, we cannot comment on results obtained with obese patients, during difficult airway management or with naïve users, although we speculate that the results found would be similar in these scenarios.

Conclusion

We found that an i-gel is significantly easier and quicker to insert than an endotracheal intubation. Leak fraction of an i-gel as compared to an ETT was similar with PCV at 15 cm H_2O. At higher pressures there was a small but significant increase in LF when comparing i-gel with an ETT. Hemodynamic response to insertion and pharyngolaryngeal morbidity was significantly less with an i-gel as compared to an ETT. Our study concludes that the i-gel provides a reasonable alternative to the ETT for controlled ventilation in adult patients undergoing routine surgical procedures provided the pressures can be limited to 15-20 cm H_2O.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Maulana Azad Medical College and associated Lok Nayak Hospital.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – A.D., A.R.B.; Design – A.D., A.R.B.; Supervision – A.R.B.; Resources – A.R.B., A.D.; Materials – A.D., A.R.B.; Data Collection and/or Processing – A.D., S.S., S.C.; Analysis and/or Interpretation – A.D., S.S., S.C.; Literature Search – A.D., S.S., S.C.; Writing Manuscript – A.D., S.S., S.C.; Critical Review – S.S., S.C.

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Hasta Onamı: Yazılı hasta onamı bu çalışmaya katılan hastalardan alınmıştır.

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