Original Article

Comparison of clinical performance of the I-gel with LMA proseal

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Abstract

Aim: To compare insertion characteristics of 2 different supraglottic devices [I-gel and Proseal laryngeal mask airway (PLMA)] and to observe any associated complications.

Study Design: This prospective, randomized study was conducted in 80 patients [Group I - I-gel insertion (n = 40) and Group P - LMA Proseal insertion (n =40)] of ASA grades I/II, of either sex in the age group 18-65 years. Both groups were compared with respect to ease of insertion, insertion attempts, fiberoptic assessment, airway sealing pressure, ease of gastric tube placement, and other complications.

Materials and Methods: All patients were asked to fast overnight. Patients were given alprazolam 0.25 mg orally at 10 p.m. the night before surgery and again 2 hours prior to surgery with 1-2 sips of water. Glycopyrrolate 0.2 mg, metoclopramide 10 mg, and ranitidine 50 mg were administered intravenously to the patients 45 minutes prior to the surgery. Once adequate depth of anesthesia was achieved either of the 2 devices, selected using a random computerized table, was inserted by an experienced anesthesiologist. In group I, I-gel was inserted and in patients of group P, PLMA was inserted.

Statistical Analysis: Student *t-test* and Mann-Whitney test were employed to compare the means; for categorical variables, Chi-square test was used.

Result: Mean insertion time for the I-gel (11.12 ± 1.814 sec) was significantly lower than that of the PLMA (15.13 ± 2.91 sec) (P = 0.001). I-gel was easier to insert with a better anatomic fit. Mean airway sealing pressure in the PLMA group (29.55 ± 3.53 cm H_2O) was significantly higher than in the I-gel group (26.73 ± 2.52 cm H_2O; P = 0.001). Ease of gastric tube insertion was significantly higher in the I-gel group (P = 0.001). Incidence of blood staining of the device, sore throat and dysphagia were observed more in PLMA group. No other complications were observed in either of the groups.

Key words: Airway sealing, cuff pressure, fiberoptic, I-gel, insertion, leak, proseal laryngeal mask airway

Introduction

The I-gel supraglottic airway device (Intersurgical Ltd, Wokingham, Berkshire, UK) was developed in 2007 to overcome the limitations of Proseal laryngeal mask airway (PLMA). It is made up of a thermoplastic elastomer (SEBS - styrene ethylene butadiene styrene) with a soft durometer (hardness), which has a gel-like feel.[1] It was designed to create a non-inflatable, anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures while avoiding compression trauma. The shape, softness and contour accurately mirror the perilaryngeal anatomy to create the perfect fit, so that compression and displacement trauma are significantly reduced and has cheaper manufacturing costs due to the simplicity of design.[2,3]

We compared the clinical performance of the I-gel and PLMA in terms of the efficacy and safety management in anesthetized patients on controlled ventilation, undergoing elective surgical procedures with respect to airway sealing pressure, ease of insertion, insertion attempts, fiberoptic assessment, ease of gastric tube placement, and complications.

Materials and Methods

The study was conducted after obtaining approval from the hospital ethical committee and a written informed consent from the patients. This prospective randomized study was conducted on 80 patients of American Society of

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Anesthesiologists physical status I/II, of either sex in the age group of 18-65 years, who were scheduled to undergo elective surgery in the supine position under general anesthesia with controlled ventilation. The exclusion criteria were patients with anticipated difficult airway, pregnancy, any pathology of the neck and upper respiratory tract or upper alimentary tract, mouth opening <2.5 cm, at risk of aspiration e.g., full stomach, hiatus hernia or gastro-esophageal reflux disease or those undergoing emergency surgery, BMI > 25 kg/m^2, cervical spine disease, and head and neck surgical procedures were excluded from the study.

All patients were asked to fast overnight. Patients were given alprazolam 0.25 mg orally at 10 p.m. the night before surgery and again 2 hours prior to surgery with 1-2 sips of water. Glycopyrrolate 0.2 mg, metoclopramide 10 mg, and ranitidine 50 mg were administered intravenously (IV) to the patients 45 minutes prior to the surgery. Baseline parameters [peripheral oxygen saturation (SpO_2), electrocardiogram lead II, heart rate, systolic, diastolic, mean blood pressure and respiratory rate] were noted. Anesthesia was induced with fentanyl 2 μg/kg and propofol 2-2.5 mg/kg IV. Neuromuscular block was achieved with rocuronium 0.6 mg/kg IV. Both I-gel and PLMA were lubricated with water-soluble jelly. Patients were ventilated using facemask with nitrous oxide 67%, oxygen 33%, and 0.4% isoflurane for 180 seconds before attempting insertion of the chosen airway device. Once adequate depth of anesthesia was achieved either of the 2 devices, selected using a random computerized table, was inserted by an experienced anesthesiologist. In group I, I-gel of appropriate size according to the weight of the patient, was inserted as per manufacturer's instructions,[1] and in patients of group P, PLMA of appropriate size, according to the weight of the patient, was inserted as per manufacturer's introducer technique.[4] Cuff of the LMA Proseal was inflated with air to 60 cm H_2O pressure and maintained at this pressure throughout anesthesia using a cuff pressure monitor. Both the devices were fixed by taping the tube over the chin and a well-lubricated gastric tube was introduced into the stomach through the gastric port. An effective airway was confirmed by bilateral symmetrical chest movements on manual ventilation, square waveform on capnography, no audible leak of gases and lack of gastric insufflation.[5]

Maintenance of anesthesia was achieved with the nitrous oxide:oxygen mixture and 0.4% isoflurane and intermittent boluses of rocuronium administered IV. During anesthesia hemodynamic parameters were recorded prior to insertion of the device and then at 1, 5, 10, and 15 minutes after the insertion of device. Thereafter, monitoring was done at 15-minute intervals till the end of surgery. Insertion time was recorded by an independent observer and defined as time interval between picking up the device and securing an effective airway. However, if insertion failed at the second attempt, patient was withdrawn from the study and insertion was recorded as a failure and a cuffed endotracheal tube of appropriate size was inserted. Insertion was scored as per Table 1.

If manipulation was required for achieving an effective airway, it was recorded as either 'yes' or 'no' and maneuvers required were noted. Airway sealing pressure was measured (at cuff pressure of 60 cm H2O in case of PLMA) by closing the expiratory valve of the circle system at a fixed gas flow rate of 3 L/min and recording the airway pressure at which equilibrium was reached. At this stage an audible leak at the mouth (sound of gas escaping from mouth heard by listening close to patient's mouth) and stomach (sound of gas escaping into esophagus heard by auscultation over epigastrium) was ascertained. Tidal volume loss was detected by inspiratory (set) - expiratory (outcome) volume on the ventilator display screen. Airway seal was scored as per Table 2.

Cuff pressure of the PLMA was checked every 30 minutes till the end of surgery and was maintained at 60 cm H_2O by removing air from the cuff using a syringe. Cuff pressure was checked using Portex Cuff Inflator/Pressure Gauge (SIMS Portex Limited, Hythe, UK). The amount of air removed was recorded. The anatomical position of the device was assessed by introducing a flexible fiberoptic bronchoscope into the airway tube to a position proximal to the terminal end. The scoring of fiberscope examination view was done as per Table 3.

Table 1: Insertion of device score

Score	
3	Insertion at first attempt without any tactile resistance
2	Insertion at first attempt with tactile resistance
1	Insertion successful at second attempt
0	Insertion failed at second attempt

Table 2: Airway sealing quality score

ASQ	
1	No leak detected
2	Minor leak of tidal volume (Vt loss less than or equal to 20%)
3	Moderate leak of tidal volume (Vt loss between 20%-40%)
4	Insufficient seal (Vt loss > 40%)

Table 3: Fiberoptic scoring system[6-8]

Score	
1	Clear view of vocal cords
2	Only arytenoid cartilages visible
3	Only epiglottis visible
4	No laryngeal structures visible

Ease of insertion of the gastric tube was recorded as either: easy/difficult/failure. Its correct placement was confirmed by aspiration of the gastric contents or by injection of air and auscultation over the epigastrium. Failure was defined as inability to advance the orogastric tube into the stomach within 2 attempts. At the end of the surgical procedure anesthesia was discontinued, neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg IV and the device was removed. Blood staining of the device, tongue, lip, and dental trauma were recorded. Regurgitation of gastric contents was also assessed. Patients were questioned after regaining full consciousness and again after 24 hours to assess pharyngolaryngeal morbidity (sore throat, dysphagia, and dysphonia).

Data is presented as mean ± SD. Age, height, weight, duration of surgery, time taken to secure effective airway, number of maneuvers required to insert the device, airway sealing pressure, attempts of gastric tube insertion, and cuff characteristics were compared using the Student *t-test* and Mann-Whitney test. Gender, ease of insertion, manipulations required to insert the device, ease of gastric tube insertion, and fiberoptic view between the groups were compared using the Chi-square test. Complications were compared using Fisher exact *test*. *P* values of ≤ 0.05 were considered significant.

Results

The demographic profiles of patients in both the groups were similar [Table 4]. In all patients the supraglottic device, I-gel or PLMA, was inserted within 3 attempts. Mean insertion time for the I-gel (11.12 ± 1.814 sec) was found to be significantly lower than the mean insertion time for PLMA (15.13 ± 2.91 sec) [*P* = 0.001; Table 5]. A statistically significant difference (*P value* = 0.0004) was found between the I-gel (grade 3 = 32/40) and PLMA (grade 3 = 25/40) groups with regard to ease of insertion. Significantly, higher [*P value* = 0.0004; Table 5] no. of manipulations were required in the PLMA group (17/40 = 42.5% cases) as compared to the I-gel group (3/40 = 7.5% cases) to insert the device and the most frequent maneuver required was extension of the head and neck. A better anatomic fit was achieved in the I-gel group (grade 1 = 97.5% cases) as compared to the PLMA group (grade 1 = 75% cases) [*P* = 0.001; Table 5]. The mean airway sealing pressure in the PLMA group (29.55 ± 3.53 cm H_2O) was found to be significantly higher than that observed in the I-gel group (26.73 ± 2.52 cm H_2O) [*P value* = 0.0001; Table 6].

Adequate ventilation was achieved in both the groups. No patient, in either group, was observed to have a major loss i.e., > 40% of the tidal volume. Airway sealing quality as determined by percentage loss of delivered tidal volume was comparable between the 2 groups [*P* = 1; Table 6]. Other parameters like heart rate, blood pressure, end-tidal carbon dioxide and SpO_2 were comparable between the 2 groups

Table 4: Demographic data and type of surgeries performed

Variables	Group *I* (*n* = 40)	Group *P* (*n* = 40)	*P* value
Age (years)	32.13 ± 11.69	32.43 ± 7.27	0.887 (NS)
Sex (M/F)	25/15	27/13	0.796 (NS)
Weight (kg)	57.1 ± 8.482	58.15 ± 11.249	0.642 (NS)
Height (cms)	162.53 ± 9.234	161.73 ± 9.08	0.684 (NS)
General surgery	13 (32.5%)	13 (32.5%)	0.746 (NS)
Plastic surgery	25 (62.5%)	24 (60%)	
Orthopedic surgery	2 (5%)	3 (7.5%)	

Table 5: Insertion characteristics

Variables	Group *I* (*n* = 40)	Group *P* (*n* = 40)	*P* value
Insertion time	11.2 ± 1.814	15.13 ± 2.91	0.001*(S)
Ease of insertion			
3	32 (80%)	25 (62.5%)	0.0004*(S)
2	8 (20%)	15 (37.5%)	
1	0	0	
0	0	0	
Manipulations			
Yes	3 (7.5%)	17 (42.5%)	0.0001*(S)
No	37 (92.5%)	23 (57.5%)	
Maneuvers			
No	37 (92.5%)	27 (67.5%)	0.0001*(S)
1	3 (7.5%)	8 (20%)	
2 or more	0	9 (22.5%)	
Anatomic fit			
1	39 (97.5%)	30 (75%)	0.001*(S)
2	1 (2.5%)	7 (17.5%)	
3	0	2 (5%)	
4	0	1 (2.5%)	

** - statistically significant*

Table 6: Maintenance characteristics

Variables	Group *I* (*n* = 40)	Group *P* (*n* = 40)	*P* value
ASP (cm H2O)	26.73 ± 2.52	29.55 ± 3.53	0.0001*(S)
ASQ score			
1	32 (80%)	32 (80%)	1 (NS)
2	8 (20%)	8 (20%)	
Gastric tube insertion			
Easy	38 (95%)	29 (72.5%)	0.001*(S)
Difficult	2 (5%)	9 (22.5%)	
Failed	0	2 (5%)	
Attempts at gastric tube insertion			
1	40 (100%)	34 (85%)	0.008*(S)
2	0	4 (10%)	

** - statistically significant*

Table 7: Recovery characteristics

Variables	Group *I* (*n* = 40)	Group *P* (*n* = 40)	*P* value
Blood staining of device			
Yes	0	8 (20%)	0.045*(S)
No	40 (100%)	32 (80%)	
Sore throat			
1 h	0	7 (17.5%)	
2 h	0	3 (7.5%)	
Dysphagia			
1 h	0	7 (17.5%)	
2 h	0	4 (10%)	

** - statistically significant*

and within normal limits during the perioperative period. No episode of hypercapnia or desaturation was observed. There were statistically significant differences regarding postoperative adverse events between the 2 groups. Higher incidence of macroscopic blood staining of the supraglottic device, sore throat, and dysphagia were observed in PLMA group as compared to the I-gel group [$P = 0.045$; Table 7]. None of the patients had dysphonia or any other complications in either of the groups. The mean intra-cuff pressure of the PLMA increased to 77.65 ± 7.57 cm H_2O after 30 minutes and 96.82 ± 6.82 cm H_2O after 90 minutes, from the initial value of 60 cm H_2O, during the course of general anesthesia. The mean amount of air removed after 30 and 60 minutes were observed to be 2.99 ± 0.72 ml and 4.01 ± 0.67 ml, respectively.

Discussion

The inflatable cuff of PLMA may be the cause of various malpositions after insertion.[2] The cuff of PLMA may impede its proper placement and lack of back-plate may lead to a fold over malposition.[9,10] The mean insertion time in the I-gel Group I was significantly lower (11.12 ± 1.814) than mean insertion time of the PLMA group (15.13 ± 2.91) cases. A statistically significant difference was found between group I (grade 3 = 32/4) and group II (grade 3 = 25/40) with regard to ease of insertion ($P = 0.0004$). None of the patients, in either of the groups, required a second attempt for inserting the device.

The median insertion time of 11 seconds has been reported with I-gel, with a first attempt insertion rate of 90% and the balance requiring a second attempt while none needed a third.[11] Since no cuff inflation is required in the I-gel, there is a shorter time required to achieve an effective airway, it is easier to insert and success at first attempt is more as compared to the PLMA.[12-15] In our study significantly more number of manipulations (*P value* = 0.0004) were required in cases in group P to insert the device. Fiberoptic scores confirmed that the I-gel has an excellent anatomic fit (Grade 1 view = 97.5%), which is significantly better than the PLMA (Grade 1 view = 75%). I-gel consistently achieves proper positioning for supraglottic ventilation and causes less hemodynamic changes as compared to other supraglottic airway devices.[16]

In our study the mean airway sealing pressure in the group P (29.55 ± 3.53) patients was found to be significantly higher than that observed in group I (26.73 ± 2.52) patients. The average airway sealing pressure was reported as 25.27 cm H_2O with I-gel and 29.6 cm H_2O PLMA.[12] The mean leak pressure has been reported as 25.6 ± 4.9 with the use of I-gel.[17] The seal pressure appears to improve over time in a number of patients due to the thermoplastic properties of the gel cuff, which may form a more efficient seal around the larynx after warming to body temperature.[13]

A gradual increase was seen in the cuff pressure of PLMA well over a 3-hour period during nitrous oxide and oxygen anesthesia.[18] We found a similar increase in values of intra-cuff pressure of PLMA at 30 and 60 minutes post-insertion. The ease of gastric tube insertion was significantly higher ($P = 0.001$) in group I (easy = 95%) as compared to group II (easy = 72.5%). The success rate of first time insertion of gastric tube was 100% with the I-gel (30/30) than with the PLMA (26/30). These observations are in close approximation to the results reported by others.[12,14,19]

Hemodynamic parameters were comparable between the 2 groups throughout the course of the surgical procedures. In the present study use of the PLMA is associated with a higher incidence of pharyngolaryngeal morbidity (blood staining of the device, sore throat, and dysphagia) in comparison to the I-gel. Blood staining of the device was more with the PLMA (18%) than with the I-gel (3%). There were no incidences of bronchospasm, laryngospasm, aspiration, regurgitation, and hoarseness in both the groups. Singh *et al.*[12] reported that the incidence of tongue, lip, and dental trauma was observed in 16.7% (5/30) patients in the PLMA group and in 3.3% (1/30) patients in the I-gel group. After removal of the I-gel a short coughing episode and a transient moderate sore throat was reported.[14] With use of PLMA reported incidence of sore throat is 23% after operation and 16% after 24 hours, with 90% of the sore throats being described as mild.[20]

Devices with an inflatable mask have the potential to cause tissue distortion, venous compression, and nerve injury, which explains the increased incidence of associated postoperative morbidity.[2] Trauma on insertion, multiple insertions, and pressure exerted by cuff against the pharyngeal mucosa,[21-26] cuff volumes[27] and pressure[26] have all been incriminated for postoperative complications.

The only parameter in which PLMA is better than I-gel is the airway sealing pressure. PLMA provides higher airway sealing pressures (oropharyngeal leak pressures) as compared to I-gel however the airway sealing pressure of I-gel is also within the normal limits and is reported to be effective in preventing aspiration. The present study has not examined the performance of the I-gel in patients with a full stomach. Our results reflect that the use of I-gel in such patients may not be appropriate.

To conclude, I-gel is comparable to the PLMA in securing a patent airway during controlled ventilation. It is better than PLMA in terms of faster insertion and ease of insertion with a low incidence of pharyngolaryngeal morbidity. It requires less manipulation and no cuff inflation is required, therefore securing an airway is rapid in most of the patients. Although, the sample size of the present study is relatively small, it clearly elucidates that the I-gel appears to be efficacious in insertion characteristics. Our study however offers almost no conclusive evidence of unflinching safety of the device, which requires data from a considerably larger cohort in a routine practice.

References

1. I-gel User Guide. 7th ed. Wokingham, UK: Intersurgical Ltd; 2009. http://www.igel.com.*accessed 16th feb, 2011*
2. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: A novel supraglottic airway without inflatable cuff. Anaesthesia 2005;60:1022-6.
3. Schmidbauer W, Bercker S, Volk T, Bogusch G, Mager G, Kerner T. Oesophageal seal of the novel supralaryngeal airway device I-Gel in comparison with the laryngeal mask airways Classic and ProSeal using a cadaver model. Br J Anaesth 2009;102:135-9.
4. LMA-ProSeal Instruction Manual. San Diego: LMA North America; 2001.
5. Keller C, Brimacombe J, Keller K, Morris R. A comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. Br J Anaesth 1999;82:286-7.
6. Brimacombe J, Berry A. A proposed fibreoptic scoring system to standardize the assessment of laryngeal mask airway position. Anesth Analg 1993;76:457.
7. Keller C, Brimacombe J, Puhringer F. A fibreoptic scoring system to assess the position of laryngeal mask devices. Inter observer variability and a comparison between the standard, flexible and intubating laryngeal mask airway. Anasthesiol Intensivmed Notfallmed Schmerzther 2000;35:692-4.
8. Ovasapian A, Klock PA Jr, Chalabi BT. ProSeal laryngeal mask airway: Fiberoptic assessment of the device position and utility. Anesthesiology 2002;96:A-1321.
9. Brimacombe J, Keller C. The ProSeal laryngeal mask airway. A randomized, crossover study with the standard laryngeal mask airway in paralyzed, anaesthetized patients. Anesthesiology 2000;93:104-9.
10. Brimacombe J, Keller C, Fullekrug B, Agrò F, Rosenblatt W, Dierdorf SF, *et al*. A multicenter study comparing the ProSeal with the Classic laryngeal mask airway in anesthetized, non paralyzed patients. Anesthesiology 2002;96:289-95.
11. Kannaujia A, Srivastava U, Saraswat N, Mishra A, Kumar A, Saxena S. A preliminary study of I-gel: A new supraglottic airway device. Indian J Anaesth 2009;53:52-6.
12. Singh I, Gupta M, Tandon M. Comparison of Clinical Performance of I-Gel™ with LMA-Proseal in Elective Surgeries. Indian J Anaesth 2009;53:302-5.
13. Gabbott DA, Beringer R. The I-gel airway: A potential role for resuscitation? Resuscitation 2007;73:161-2.
14. Richez B, Saltel L, Banchereau F, Torrielli R, Cros AM. A new single use supraglottic airway device with a non-inflatable cuff and an esophageal vent: An observational study of the I-gel. Anesth Analg 2008;106:1137-9.
15. Uppal V, Gangaiah S, Fletcher G, Kinsella J. Randomized crossover comparison between the I-gel and the LMA-Unique in anaesthetized, paralysed adults. Br J Anaesth 2009;103:882-5.
16. Jindal P, Rizvi A, Sharma JP. Is I-gel a new revolution among supraglottic airway devices? A comparative evaluation. Middle East J Anesthesiol 2009;20:53-8.
17. Helmy AM, Atef HM, El-Taher EM, Henidak AM. Comparative study between I-gel, a new supraglottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients. Saudi J Anaesth 2010;4:131-6.
18. Ouellete RG. The effect of nitrous oxide on laryngeal mask cuff pressure. AANA J 2000;68:411-4.
19. Asai T, Liu EH. I-gel, a new supraglottic airway. Masui 2010;59:794-7.
20. Evans NR, Gardner SV, James MF, King JA, Roux P, Bennett P, *et al*. The ProSeal laryngeal mask: Results of a descriptive trial with experience of 300 cases. Br J Anaesth 2002;88:534-9.
21. Gardy DM, McHardy F, Wong J, Jin F, Tong D, Chung F. Pharyngolaryngeal morbidity with laryngeal mask airway in spontaneously breathing patients. Anesthesiology 2001;94:760-6.
22. Nott MR, Noble PD, Pamar M. Reducing the incidence of sore throat with larnygeal mask airway. Euro J Anaesthesiol 1998;15:153-7.
23. McHardy FE, Chung F. Postoperative sore throat: Cause, prevention and treatment. Anaesthesia 1999;54:444-53.
24. Gatward JJ, Cook T, Seller C, Handel J, Handel J, Simpson T, *et al*. A cohort study of I-gel in 100 elective patients. Br J Anaesth 2008;63:1124-30.
25. Keller C, Puhringer F, Brimacombe JR. The influence of cuff volumes on oropharyngeal leak pressure and fibreoptic position with the laryngeal mask airway. Br J Anaesth 1998;81:186-7.
26. Burgard G, Mollhoff T, Prien T. The effect of laryngeal mask cuff pressure on postoperative sore throat incidence. J Clin Anesth 1996;8:198-201.
27. Brimacombe J, Holyoake L, Keller C, Brimacombe N, Scully M, Barry J, *et al*. Pharyngolaryngeal, neck, and jaw discomfort after anesthesia with the face mask and laryngeal mask airway at high and low cuff volumes in males and female. Anesthesiology 2000;93:26-31.

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