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Original research paper

Comparison of clinical perfomance of I-Gel with LMA proseal a prospective clinical study

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Abstract

Airway management is of prime importance to an Anaesthesiologist. Unanticipated difficult laryngoscopy and endotracheal intubation remains a primary concern of anaesthesiologist. The reported incidence of a difficult laryngoscopy or endotracheal intubation varies from 1.5% to 13% in patients undergoing surgery. Failure to intubate is detected in 0.05 - 0.35% of the patients. Thus Insertion of a supraglottic device in these situations is a recognized alternative and may be a life-saving procedure preoperative. Sixty patients between 18-60 years of age and either sex were included in our study. We assessed I-gel and Proseal LMA in adults for airway sealing pressure, ease of insertion, insertion attempts, blood staining of the device, tongue, lip and dental trauma. All patients were asked to fast overnight. Mean insertion time for the I-gel (14.12 ± 2.24 sec) was significantly lower than that of the PLMA (26.1 ± 3.3 sec) (P = 0.0001). I-gel was easier to insert with a better anatomic fit. Mean airway sealing pressure in the PLMA group (30 ± 4.27 cmH2O) was significantly higher than in the I-gel group (24 ± 4.37cm H2O; P = 0.0001). From our study we conclude that: I-gel scores better than Proseal in insertion time, causes lesser incidence of postoperative sore throat due to its non inflattable cuff and facilitates effective gastric drainage.

Keywords: Airway sealing, cuff pressure, i-gel, insertion, leak, proseal laryngeal mask airway

Introduction

The major responsibility of the anaesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing functional respiration is the airway.
Management of the airway has come a long way since the development of endotracheal intubation by Macewen in 1880, to present day use of modern and sophisticated airway devices [1].
Using an endotracheal tube to secure a patient's airway is still the gold standard. However, this maneuver requires skill and continuous training and practice and usually requires direct laryngoscopy, which may cause laryngo-pharyngeal lesions. Laryngoscopy and endo-tracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, stress hormones leading on to hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension. Difficulties encountered during intubation can be due to a number of

factors and may be difficult to predict. It is important to have a strategy prepared and to be familiar with the equipment. This will help to avoid potential morbidity or mortality from the sequelae of hypoxia and/or cardiovascular catastrophe that may result from a failed intubation [2].

The anaesthesiologist must be familiar with the major decision making components of the difficult airway algorithm. Over the years many attempts have been made to address various factors responsible for difficult intubations and this has resulted in a number of different techniques. It is best to use affordable, safe and useful adjuncts that are best suited to our particular anaesthetic set up [3].

Insertion of a supraglottic device in these situations is a recognized alternative and may be a life-saving procedure. Some supraglottic devices allow for subsequent tracheal intubation using a blind or a fibreoptic technique [4].

Supraglottic airway devices have become a standard fixture in airway management. These devices sit outside the trachea but achieves an air tight airway. The first successful supraglottic airway device the laryngeal mask airway (LMA) classic became available in 1989, first described by Archie Brain.

The (LMA) and similar supraglottic airway devices use an inflatable cuff to wedge in to the upper esophagus and provide a perilaryngeal seal. These devices are introduced blindly in to the hypopharynx to form a seal around the larynx, so permitting spontaneous or positive pressure ventilation without penetration of the larynx and the oesophagus.

The ProSeal laryngeal mask airway [PLMA] [intavent orthofix Maidenhead, UK] I-gel airway [intersurgical ltd, Wokingham, Berkshire, UK] are two recently introduced devices for maintaining the airway during controlled ventilation under general anaesthesia [5].

I-GEL supraglottic airway (Inter surgical Ltd., Wokingham, UK) is a relatively new device for airway management. It was developed by Dr. Mohammed Aslam Nasir in January 2007. It is made from Styrene Ethylene Butadiene Styrene, thermoplastic elastomer which is soft, gel like, transparent and is anatomically preformed to mirror the peri-laryngeal structures. It can be described as an uncuffed peri-laryngeal sealer according to Miller's classification. i.e. it also has a port for gastric tube placement.

The ProSeal laryngeal mask airway (PLMA) was introduced by Archie Bain to improve the clinical practice in 2000 with its improved feature modified cuff to improve the seal around the glottis, its seal is more effective than a classic LMA. The airway tube is wire- reinforced, like a flexible laryngeal mask airway. There is an additional drain tube placed laterally to the airway tube which is designed to allow insertion of a gastric tube and to vent gas or liquid from the upper esophagus.

In the present study we compare I-gel and Proseal LMA in adults for airway sealing pressure, ease of insertion, insertion attempts and blood staining of the device, tongue, lip and dental trauma [6].

Methodology

After obtaining ethical committee approval, the patients were randomized into one of the two groups.

- **Group A:** I-GEL for airway management.
- **Group B:** PLMA for airway management.

Patients were advised for preoperative overnight fasting for 10 hours. They were given aspiration prophylaxis with Tab Ranitidine 150 mg on the night before surgery and Inj. Glycopyrrolate 4 mcg/kg i.v. and Inj Midazolam. 02mg/kg i.v., was given one hour before induction.

Standard monitoring was applied before induction and included ECG, pulse oximeter, capnography and Non-invasive Blood pressure monitoring.

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Intravenous access was obtained with 18G peripheral venous cannula in the forearm. The patient was placed in supine position with the patient's head on a pillow of 10 cms height.
Pre-oxygenation was done for 3 minutes with 100% oxygen. All patients were given Inj. Fentanyl 2 mcg/kg iv. Anaesthesia was induced with Inj. Propofol 2mg/kg iv and neuromuscular blockade was achieved with Inj Succinylcholine 2 mg/kg iv. After induction all vitals of the patient are taken again. An appropriate size supraglottic airway device was then inserted by the author.

Group A (I- GEL)

The patient was positioned in the 'sniffing the morning air' position with head extended and neck flexed. The chin was gently pressed down before proceeding to insert I-GEL.
The lubricated I- GEL was firmly grasped along the integral bite block and the leading soft tip was introduced into the mouth of the patient in a direction towards the hard palate.
The device was glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance was felt. After connecting the circuit to the IGEL, adequate placement of the device was confirmed with chest wall excursions, square wave capnography and no oropharyngeal leak. If there was early resistance during insertion, the following manoeuvres were tried: (a) Jaw thrust, (b) Insertion with deep rotation, and (c) Triple manoeuvre. The second attempt was made with the reinsertion of either the same or different size I-GEL.

Group B (PLMA)

The LMA ProSeal may also be inserted using the LMA ProSeal Introducer technique place the tip of the Introducer into the strap at the rear of the cuff. Fold the tubes around the convex surface of the blade and fit the proximal end of the airway tube into the matching slot in the tool. The LMA ProSeal is shown mounted in the Introducer.
Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it. During insertion, the back of the mask should be in contact with the hard palate and the bowl of the mask should be facing the tongue.
Verify the position of the mask and slide the cuff further inward against the palate. Push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.
A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff has not folded over. Keeping the Introducer blade close to the chin, rotate the device inward in one smooth circular movement. During insertion, follow the curve of the rigid insertion device. The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask. Do not use the handle as a lever to force the mouth open.
Advance into the hypopharynx until a definite resistance is felt. Before removing the Introducer, the non- dominant hand is brought from behind the patient's head to stabilize the airway tube. This prevents the LMA Pro Seal from being pulled out of place when the Introducer is removed. It also permits completion of insertion in the event that full insertion has not been achieved by the Introducer alone. At this point the LMA Pro Seal should be correctly located with its tip firmly pressed up against the upper esophageal
An attempt at insertion was considered un-successful if the airway had to be taken out off the mouth because of an audible leak or the absence of square wave on capnography and re-inserted. The same device is re-inserted or a different size is chosen. Two more insertion attempts were allowed. If the insertion failed after three attempts, the insertion was considered a failure and intubation was proceeded with an endo-tracheal tube.

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Results

Table 1: Supra glottic device insertion time

Group	Number	Mean time	Std Deviation	P value
I gel	30	14.12 sec	2.24	0.0001
Pro seal	30	26.1 sec	3.3	

The maximum time for I gel insertion was 19 seconds and for Proseal was 33 seconds. The minimum time for I gel insertion was 10 seconds and for Proseal insertion was 22 seconds. The mean time for placement of I gel being 14.12 seconds and Proseal 26.1 seconds. The p value was statistically significant i. e. 0.0001.

Table 2: Number of attempts for supra glottic airway device placement

No of attempts	I gel	Pro seal	P value
1	30	30	1
2	0	0	
3	0	0	

In the Proseal group, the placement of supra glottic airway device was done successfully in the first attempt in all patients. Effective ventilation was possible in all the cases. In I gel group also placement of the airway device was done successfully in the first attempt in all patients.

Table 3: Air way leak pressure

Group	Number	Airway leak pressure mean	Std Deviation	P value
I gel	30	24 cm H20	4.37	0.0001
Pro seal	30	30. cm H20	4.27	

The maximum airway leak pressure in the I-gel group was 34 cm H20 and the least airway leak pressure was 16 cm H20. The maximum airway leak pressure in Proseal group was 38 cm H20 and the minimum airway leak pressure was 22 cm H20. The mean airway leak pressure in the I gel group and Proseal group were 24 and 30. cm H20 respectively. The p value being 0. 0001 was statistically significant.

Table 4: Ease of insertion of gastric drainage tube

Group	Number	Easy	Difficult	Failure
I gel	30	30	0	0
Pro seal	30	30	0	0

Out of the thirty cases, the drainage tube could be easily inserted in all cases in the I-gel group, grading it easy. In the Proseal group, the gastric drainage tube could be inserted in the first attempt in all thirty cases grading it easy. In none of the cases, there was a failure to insert the gastric drainage tube.

Table 5: Secondary parameters

Secondary parameters	I gel	Pro seal
Desaturation < 95%	0	0
Dental trauma	0	0
Blood staining of device	0	2
Laryngospasm	0	0

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Gastric insufflation	0	0
Post op sore throat	0	4

There was no incidence of desaturation, dental trauma, gastric insufflation or laryngospasm in both the groups. Blood staining was noted in two patients in Pro Seal group. Four patients in the Proseal group complained of post-operative throat pain.

Discussion

The overall success rate for supraglottic airway device insertion was similar in both the groups with no statistical significance, in our study. The I gel could be inserted successfully in all the cases. Our results were comparable with that of Richez *et al.* [7] who carried out one of the earliest studies to evaluate the I-gel. They found that insertion success rate was 97%. Insertion was easy and was performed at the first attempt in every patient. I-gel is easily and rapidly inserted, providing a reliable airway in over 90% of cases. whose overall success rate of insertion was 97% and also with that obtained by Gatward. J. *et al.* [8] who evaluated size 4 I-gel airway in 100 non-paralyzed patients and found that first insertion attempt was successful in 86% of patients, the second attempt in 11% of patients and the third attempt in 3% of patients.

Acott [9] assessed the use of I-gel as an airway device during general anesthesia. In accordance with our results, they reported that a single insertion attempt was required in the majority of patients. Choosing the appropriate size of the supra glottic airway device was important as inappropriate sizing could lead to reduction in the first attempt success rate for the insertion of the device. In our study we choose the size based on the weight of the patient and the manufacturers recommendation. There is an overlap of the sizing guidelines for size 3 and 4 for I gel which is confusing for the users. Janakiraman *et al.* [10] concluded that resizing the LMA size improved the overall success rate. The Proseal in our study could be inserted successfully in all the patients in the first attempt using an introducer. Brimacombe *et al.* [11] showed that the first-time success rates were higher and that the effective airway time was shorter with the introducer. The insertion is easier with the introducer, because it occupies lesser space than the finger and avoids the insertion of the finger inside the oral cavity, directs the cuff around the oropharyngeal inlet and facilitates a full depth of insertion. This was similar to the results of Evans NR [12] who showed high success rates with the finger insertion or the introducer method for Proseal.

In our study, the mean airway leak pressure in the I-gel group was 24 cm H 2 0. This is consistent with the results of Gatward *et al.* [13] who reported a mean leak pressure of 24 cm H_2O and in a study on 100 patient by Gabbott and Beringer [14] reported that 98 of 100 devices were adequately positioned on the first or second attempt and peak airway pressures in excess of 30 cm H_2O were possible in the vast majority of patients. The mean and median leak on sustained pressure (with the circle gas flows of 4 L min-1 and the APL valve closed) was 24 cm H_2O. Keller C [9] compared the four methods a] detection of audible noise by listening over the

mouth b]detection of exhaled CO_2 by placing a gas sampling line for the capnograph inside the mouth c]detection of audible noise on neck auscultation d]observation of anero id manometer dial as the pressure increased to note the airway pressure at which the dial reached stability and concluded that all four methods were excellent. The I gel with its high airway leak pressure as observed by the manometer stability test in our study was 24 cm

H 2 O which was well within the normal limits for effective controlled ventilation. Richez [7] in his observational study on I-gel showed that high airway leak pressure and low peak pressure ensured safe ventilation. A preliminary anatomical study in cadavers has shown that the I-gel is capable of achieving a good peri-laryngeal seal without the requirement of an inflattable cuff.

The I gel made of thermoplastic elastomer with a soft durometer material is designed anatomically to fit the perilaryngeal and hypopharyngeal structures without the use of an inflattable cuff. This may explain the reason for improved seal. The non inflattable cuff is semirigid and cannot be folded over or over inflatted. The seal seemed to improve with time probably due to the thermoplastic cuff warming to body temperature. The airway seal was better with the Proseal LMA with its airway leak pressure of 30 cm H_2O than I gel which was statistically significant. The higher seal pressure for the PLMA is most likely due to the deeper bowl, a bigger cuff with its dorsal and ventral components, the proximal wedge shape of the cuff, the corresponding larger surface area in comparison to I-gel and also due to the inflattable nature of the cuff in comparison to the cuffless I gel. Shin *et al*. [15] in their study showed that the airway leak pressure of Proseal was around 29 cm H_2O. Our results with the airway leak pressure of Proseal is consistent with their reports. The larger conical shaped distal cuff fills the hypopharynx more completely and the larger wedge shaped proximal cuff fills the proximal laryngopharynx more completely, both to form a better seal with their respective tracts. The PLMA probably forms a better seal because the larger ventral cuff stops gaps in the proximal pharynx and the dorsal cuff pushes the ventral cuff more firmly into the periglottic tissues. The bulky cuff design of the PLMA provides an excellent sealing effect for positive pressure ventilation.

The gastric tube could be inserted in all the cases in the I-gel group of our study and in most of the cases it was in the first attempt and graded easy. Similarly the gastric tube insertion was possible in the first attempt in all the cases in the Proseal group with no statistical difference between the groups. Richez [7] in his observational study on I gel reported that insertion of a gastric tube was possible in every case. Success rat e of gastric tube insertion through I gel was 95% in a study by Amr Helmy [16].

Bimla Sharma [17] also reported that the gastric tube could be inserted through both the I-gel and Proseal in all patients which was consistent with our results.

The mean insertion time in our study was significantly less for I-gel in comparison with the Proseal. Gatward [8] reported a median insertion time of 15 seconds and Uppal [18] reported a median insertion time of 12.2 s for I gel which was comparable to our study, The I-gel being an uncuffed peri-laryngeal sealer, the insertion was easy and quick. It also provided a reliable airway.

Conclusion

The mean insertion time for I-gel was significantly less than Proseal (p<0.05). The airway leak pressure of I-gel was significantly less when compared with Proseal (p<0. 05). There was no statistical difference between the two groups in number of attempts required for the placement of the supraglottic airway device and in the ease of insertion of the gastric tube.

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