

Original Research Article

Comparison of I-gel and ProSeal laryngeal mask airway during volume controlled ventilation

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	International Archives of Integrated Medicine, Vol. 5, Issue 5, May, 2018. Copy right © 2018, IAIM, All Rights Reserved. Available online at http://iaimjournal.com/
	ISSN: 2394-0026 (P) ISSN: 2394-0034 (O)
	Received on: 10-04-2018 Accepted on: 17-04-2018 Source of support: Nil Conflict of interest: None declared.
How to cite this article: Ranjini O.M., Paul Praveen, T. Murugan. Comparison of I-gel and ProSeal laryngeal mask airway during volume controlled ventilation. IAIM, 2018; 5(5): 38-44.	

Abstract

Introduction: I-gel and the ProSeal laryngeal mask airway (PLMA) are two supra-glottic airway devices with gastric channel used for airway maintenance in anesthesia. This study was designed to evaluate the efficacy of I-gel compared with PLMA for airway maintenance in patients under general anesthesia with controlled ventilation.

The aim of the study: To compare the supra-glottic airway devices, I-Gel and ProSeal Laryngeal mask airway with respect to Ease of insertion, Time taken for insertion, Airway leak pressure, Hemodynamic response during intubation.

Materials and methods: A total number of, 40 patients were randomized into two groups of 20 each. After induction of anesthesia using a standardized protocol for all the patients, one of the supra-glottic airway devices was inserted. Insertion parameters, ease of gastric tube insertion, airway leak pressure, hemodynamic changes, were noted.

Results: There was no significant difference in the incidence of adverse effects in both the groups. One incidence of airway trauma was noted in I-gel group. No gastric insufflations and laryngo or bronchospasm in both groups.

Conclusion: Based on the result of our study we conclude that I-gel had an acceptable airway leak pressure of 23 cm H₂O when compared to ProSeal whose airway leak pressure is significantly higher i-e 29 cm H₂O. Both the devices provided optimal oxygenation and no fall in saturation was observed in both the groups.

Key words

I-gel, ProSeal Laryngeal Mask, Airway Leak Pressure.

Introduction

The airway is the most vital element in providing functional respiration. First, orotracheal intubation was done by William McEwan in 1878 [1] and since then, maintenance of airway has been the utmost priority of the anesthesiologists. The tracheal intubation is the gold standard method for maintaining a patent airway during anesthesia [2]. However, this maneuver requires skill and continuous training and practice and usually requires direct laryngoscopy, which may cause laryngopharyngeal lesions [3]. Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia, and myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension [4]. Difficulties encountered during intubation can be due to a number of factors and may be difficult to predict and they pose a special challenge to the anesthesiologist. Problems encountered in intubation can cause serious soft tissue damage [5] and are the principal causes of hypoxemic anesthetic death and brain damage [6, 7]. Alternative techniques to allow continuous ventilation and oxygenation were devised. Supraglottic devices in these situations are a recognized alternative and may be life-saving. The laryngeal mask airway was conceived and designed by Archie Brain in the United Kingdom in 1981. Following prolonged research, it was released in 1988. He realized its potential in the management of difficult airway at an early stage [8-10]. It has now got a role in the routine management of airway management and has established as an airway device in the elective setting where the procedure does not warrant tracheal intubation [11]. Initially designed for use in the operating room, it has recently come into use in the emergency department as an important device for the management of difficult airway and also in out of hospital care as it is easy to use

and quick to place even for the inexperienced person [12-14]. We chose to compare the I gel supra-glottic airway device with the Pro-seal laryngeal mask airway (LMA) because both the devices attain a good seal over the peri-laryngeal structures and both have a gastric channel for the drainage of gastric contents. So a prospective randomized single-blind study was designed and then I gel was compared with Pro-seal LMA with respect to esophageal leak pressure in patients undergoing elective surgery under general anesthesia. I gel is a new supra-glottic device (Intersurgical Ltd, Wokingham UK) made of thermoplastic elastomer, (styrene, ethylene, butadiene styrene) with a non-inflatable cuff to achieve a leak free seal over the larynx. It is described as an un-cuffed peri-laryngeal sealer according to Miller's classification [15]. Insertion of the I-gel is usually easy and quick; furthermore, its wide bore facilitates direct passage of a standard size tracheal tube. It can be a useful adjunct to tracheal intubation in patients with difficult airway and documented in several case reports [16-18]. The Pro-seal LMA (IntraVentortho fix Maidenhead UK) is used as a safe alternative to the tracheal tube for many laparoscopic procedures with good airway sealing pressures. A second posterior cuff is present to improve the seal. It has an incorporated gastric channel for drainage of gastric content.

Materials and methods

This study was conducted at Govt. Kilpauk Medical College and Hospital, Chennai and was a single-blind randomized prospective comparative study. After obtaining the institutional ethical committee approval and written informed consent, forty patients under ASA physical status I and II of either sex undergoing elective surgical procedures under general anesthesia were enrolled in the study. The supra-glottic airway device insertions were

done by the author and the study was conducted from August 2017 to November 2017.

Inclusion criteria

- Age 18 to 60 years.
- Both sexes
- ASA I and II.
- MPC class I and II airway.
- Patients undergoing elective surgery under general anesthesia.

Exclusion criteria

- BMI >30.
- Presence of acute or chronic airway disease.
- Patients with a history of gastro-oesophageal reflux disease.
- Hiatus hernia.
- Musculoskeletal abnormalities affecting cervical vertebra.
- Patients with a history of sleep apnoea.

The patients were randomized into one of two groups using a closed envelope with the predetermined group number and then single-blinded. I-gel group – Group A, ProSeal group – Group B; All patients have advised overnight fasting and aspiration prophylaxis with Tab. Ranitidine 150 mg and Tab. Metoclopramide 10 mg were given the night before surgery. Complete medical history and physical examination were done for all patients. They were pre-medicated with Inj. Glycopyrolate 0.2 mg IV, Inj. Ranitidine 50 mg IV and Inj. Metoclopramide 10 mg IV about half an hour before induction. Routine monitoring included

ECG, Pulse oximetry, Capnography Temperature and End Tidal CO₂ was done. The patients were pre-oxygenated for three minutes with 100% oxygen and all patients were given Inj. Midazolam 0.02 mg/kg IV and Inj. Fentanyl 2 mics/kg IV. They were induced with Inj. Propofol 2 mg/kg IV and Inj. Atracurium 0.5 mg/Kg IV. Patients were ventilated with a bag and mask with 2% sevoflurane with oxygen for three minutes and an appropriate supra glottis airway device depending on the weight of the patient was inserted.

Results

The airway leak pressure of ProSeal LMA was significantly higher than that of I-gel LMA. Hemodynamic changes during insertion of both the devices were comparable, without any alterations. The insertion of I-gel took much shorter time than ProSeal LMA due to the presence of the non-inflatable cuff. Both types of LMAs could be inserted with ease in the first attempt. There was no significant difference in the incidence of adverse effects in both the groups. One incidence of regurgitation but no signs of aspiration occurred in I-gel group which was not statistically significant. One incidence of airway trauma was noted in I-gel group. No gastric insufflation and laryngo or bronchospasm in both groups. Both devices provided optimal oxygenation and no fall in saturation observed in both the groups (**Table – 1, 2 and Graph – 1, 2, 3**).

Table – 1: Characteristic features of patients.

	Group A (I-gel)	Group B (ProSeal)	P value
Age	40.15±11.7	38.95±14.93	0.38
Weight	58.55±7.43	54.55±10.47	0.08
BMI	22.57±2.32	22.01±3.42	0.27
Gender (M/F)	11/9	10/10	0.75

Discussion

In our study comparing the, I-gel with ProSeal the mean age, weight, BMI and sex ratio was comparable among both the groups. Our results

showed that I-gel was as effective as ProSeal in anesthetized paralyzed patients with class 1 and 2 airway. The overall success rate for supra-glottic airway device insertion was similar in both the

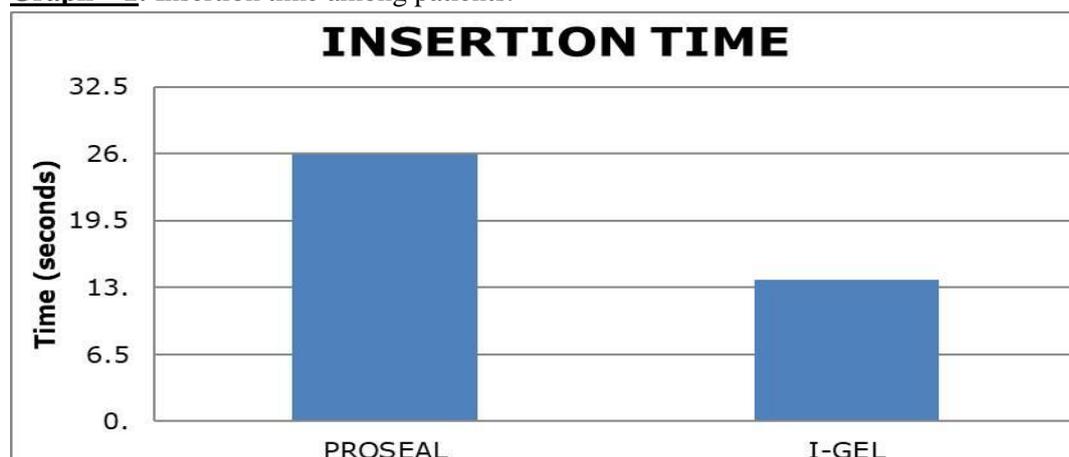
groups with no statistical significance. Then I gel could be inserted successfully in all the cases. Our results were comparable with that of Richez [19] whose overall success rate of insertion was 97% and also with that obtained by Gatward J., et al. [20]. Shin WJ [21] assessed the use of I-gel as an 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 a 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 manufacturer's recommendation. Since there was an audible leak in one patient, size 3 was replaced with size 4. There is an overlap of the sizing guidelines for size 3 and 4 for I gel which is confusing for the users.

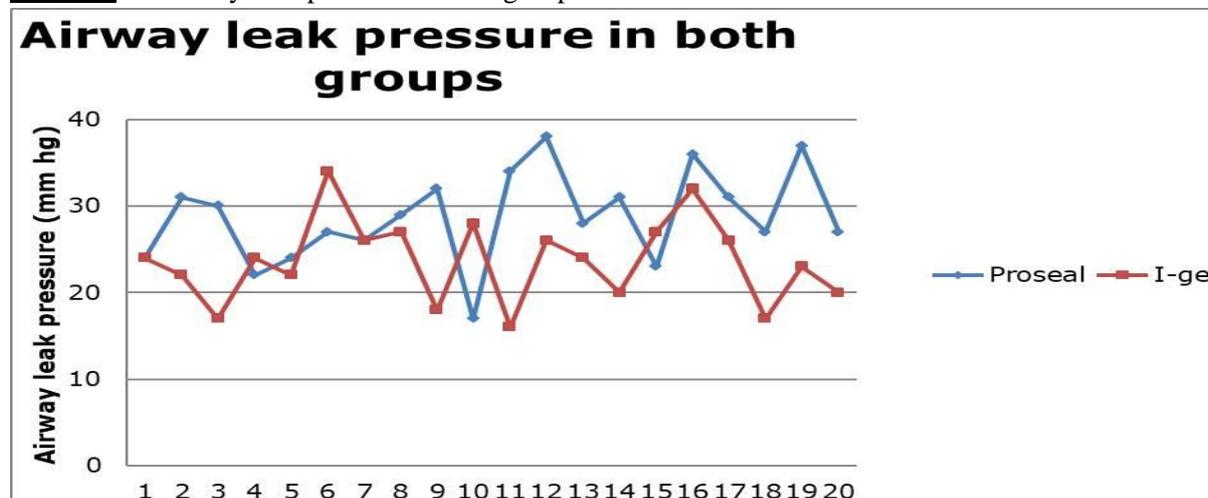
Table – 2: Primary characteristics of patients.

	I-gel	ProSeal	P VALUE
Airway leak pressure	23.65±4.84	28.7±5.33	0.001
Insertion time	13.8±2.19	25.9±2.63	0.0001
No of attempts			
1	19	20	0.31
2	1	0	
3	0	0	

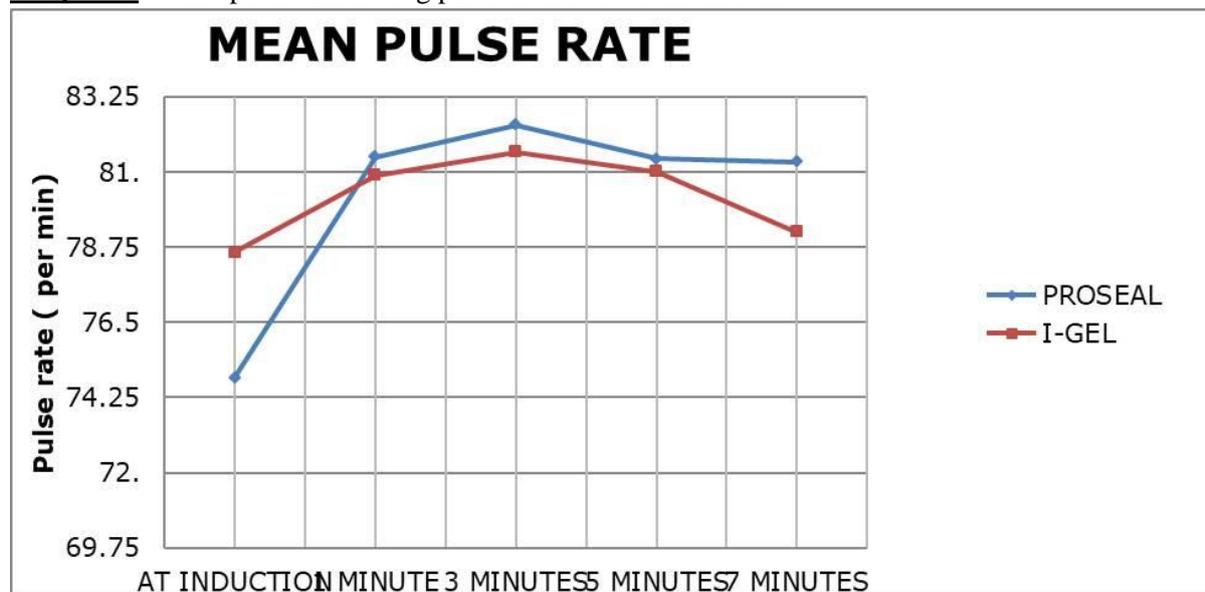
Graph – 1: Insertion time among patients.



Graph – 2: Airway leak pressure in both groups.



Graph – 3: Mean pulse rate among patients with time variations.



Janakiraman, et al. [24] 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. This was similar to the results of Evans NR who showed high success rates with the finger insertion or the introducer method for ProSeal [21]. Amr M Helmy [22] in his observational study on I-gel showed that high airway leak pressure and low peak pressure ensured safe ventilation. An preliminary anatomical study in cadavers has shown that the I-gel is capable of achieving a good perilaryngeal seal without the requirement of an inflatable cuff. The efficacy of seal depends on the fit between the oval-shaped groove surrounding the glottis and the oval-shaped cuff of the laryngeal mask airway. I-gel made of a thermoplastic elastomer with a soft material is designed anatomically to fit the perilaryngeal and hypopharyngeal structures without the use of an inflatable cuff. This may explain the reason for improved seal. The non-inflatable cuff is semirigid and cannot be folded over or overinflated. 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 29 cm H₂O 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 inflatable nature of the cuff in comparison to the cuffless I-gel [22]. H. Francksen, et al. [23] in their study showed that the airway leak pressure of ProSeal was 29 cm H₂O. Our results with the airway leak pressure of ProSeal are 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 from 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 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 ProSeal group with no statistical difference between the groups [23]. C Janakiraman [24] 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 was significantly less for I-gel in comparison with the ProSeal. Gatward JJ [20] reported a median insertion time of 15 seconds and Utting JE [6] reported a median insertion time of 12.2s for I gel which was comparable to our study, The I-gel an uncuffed peri-laryngeal sealer, the insertion was easy and quick. It also provided a reliable airway. In our study, the hemodynamic response to insertion at one, three and five minutes was comparable between the groups with no statistical significance. Won Jung Shin compared the three devices I-gel, ProSeal and classic LMA and concluded that there were no significant differences in the hemodynamic data immediately after insertion of devices among the three groups [24]. In our study blood on I-gel could be due to the second attempt required in the case. The incidence of visible blood with the use of other supra-glottic airway devices has been quoted from 12% to 18%, depending upon the type of SAD, the technique of insertion, and ease of insertion. There were two incidents of gastric insufflation in the ProSeal group and none in the I-gel group. The incidence of clinically detectable gastric insufflations and regurgitation with the use of LMAs in general is 0-0.3% and 0.07%, respectively. A malposition of the supra-glottic airway device increases the risk of leakage. If the leakage is sufficiently large, a ballooning of the stomach may occur. This can lead to a deterioration of the respiratory mechanics and increase the likelihood of regurgitation and thus the risk of aspiration. Depending upon their materials they can absorb anesthetic gases, leading to increase in mucosal pressures. In contrast the non-inflatable cuff of the I-gel is semi-rigid and cannot be folded over, or overinflated, thus diminishing the risk of both airway obstruction and mucosal damage. Post-operative sore throat was observed in three cases in ProSeal group. The inflatable cuffs of the pLMA and cLMA have the potential to cause complications such as mucosal injury [25].

Conclusion

Based on the result of our study we conclude that I-gel had an acceptable airway leak pressure of 23 cm H₂O when compared to ProSeal whose airway leak pressure is significantly higher i.e 29 cm H₂O. However, I-gel requires less time for insertion, causes the lesser incidence of a postoperative sore throat due to its non-inflatable cuff and facilitates effective gastric drainage. I-gel may serve to be an effective alternative as a supra-glottic airway device that can provide an adequate seal for controlled ventilation.

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