

I-gel versus laryngeal mask airway-Proseal: Comparison of two supraglottic airway devices in short surgical procedures

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Abstract

Background and Aims: Supraglottic airway devices have been established in clinical anesthesia practice and have been previously shown to be safe and efficient. The objective of this prospective, randomized trial was to compare I-Gel with LMA-Proseal in anesthetized spontaneously breathing patients.

Material and Methods: Sixty patients undergoing short surgical procedures were randomly assigned to I-gel (Group I) or LMA-Proseal (Group P). Anesthesia was induced with standard doses of propofol and the supraglottic airway device was inserted. We compared the ease and time required for insertion, airway sealing pressure and adverse events.

Results: There were no significant differences in demographic and hemodynamic data. I-gel was significantly easier to insert than LMA-Proseal ($P < 0.05$) (Chi-square test). The mean time for insertion was more with Group P (41 + 09.41 secs) than with Group I (29.53 + 08.23 secs) ($P < 0.05$). Although the airway sealing pressure was significantly higher with Group P (25.73 + 02.21 cm of H₂O), the airway sealing pressure of Group I (20.07 + 02.94 cm of H₂O) was very well within normal limit (Student's t test). The success rate of first attempt insertion was more with Group I ($P < 0.05$). There was no evidence of airway trauma, regurgitation and aspiration. Sore throat was significantly more evident in Group P.

Conclusion: I-Gel is a innovative supraglottic device with acceptable airway sealing pressure, easier to insert, less traumatic with lower incidence of sore throat. Hence I-Gel can be a good alternative to LMA-Proseal.

Key words: Airway sealing pressure, I-gel, laryngeal mask airway-Proseal, supraglottic airway device

Introduction

It has become something of a holy grail in recent years to maintain airway patency with supraglottic airway devices especially LMA-Proseal in day care short surgical procedures without the use of the neuromuscular blockade, in order to reduce the postoperative hospital stay and the postoperative complaints of sore throat.^[1] The safety and efficacy of I-gel is yet to be explored. Since LMA-Proseal has almost similar design as I-gel, we decided to compare both these devices.

I-gel is a novel supraglottic airway device with anatomically designed, non-inflatable mask, which is soft gel like and transparent made of medical grade thermoplastic elastomer called styrene ethylene butadiene styrene. The soft noninflatable cuff fits snugly onto the perilaryngeal framework and its tip lies in the proximal opening of the esophagus, thus isolating oropharyngeal opening from the laryngeal opening. The device has a buccal cavity stabilizer which has a propensity to adapt its shape to the oropharyngeal curvature of the patient. This buccal cavity stabilizer houses airway tubing and a separate gastric channel.^[2-4]

In this prospective randomized single blinded open study, we have compared the safety and efficacy of I-gel and LMA-Proseal in terms of ease, time and the attempts required for insertion, airway sealing pressure and airway complications.

Material and Methods

After approval from the institution's ethics committee, written informed, valid consent was obtained from all patients after explaining the study protocol.

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Sixty patients of either sex, 18-60 years, American Society of Anesthesiologists Grade I/II undergoing short surgical procedures lasting for 30-120 min were included in the study.

Patients with anticipated difficult airway, restricted mouth opening, pregnant females, cervical spine disease, obese with body mass index >30 kg/m² and patients with history of regurgitation were excluded from the study.

Patients were randomly allocated into two groups each based on the computer generated codes. Group I in whom I-Gel was inserted and Group P in whom LMA-Proseal was inserted. Anesthesiologist in post-anesthesia care unit monitoring the post-operative parameters and incidence of sore throat, and the patient were all blinded to the group assignment.

Pre-anesthetic assessment included medical/surgical history, general/systemic examination, airway examination and investigations, such as complete hemogram, chest X-ray and electrocardiogram.

After peripheral venous cannulation, monitors including blood pressure (BP) cuff, cardioscope, and pulse oximeter were attached and baseline parameters such as pulse, BP, oxygen saturation, and respiratory rate were noted.

After standard premedication with injection glycopyrrolate 0.004 mg/kg, ondansetron 0.08 mg/kg, ranitidine 1 mg/kg, midazolam 0.02 mg/kg and fentanyl 2 mcg/kg, all patients were pre-oxygenated with 100% oxygen for 3 min. Each patient then received induction dose of injection propofol (2-2.5 mg/kg) until the loss of eyelash reflex and achievement of adequate jaw relaxation. To prevent bias, device was inserted by a qualified anesthesiologist with minimum 2 years' experience. The patient's head was placed in sniffing the morning air position. The supraglottic airway device was inserted after lubricating the cuff with a water based jelly. LMA-Proseal cuff was inflated with half the recommended volume of air and in case of inadequate seal entire recommended volume of air was used to inflate the cuff. In case of further leak, the device was removed and one size bigger was inserted. Additional doses of propofol were used in case of reinsertion if required. The device was then connected to the breathing circuit and capnometer assembly and secured after confirming bilaterally equal air entry. Nasogastric tube was inserted. An effective airway was confirmed from the bilaterally symmetrical chest movements, square wave form on the capnograph and a normal saturation.

Ease of insertion was defined as no resistance to the insertion of device in the pharynx in single attempt. The time taken for the insertion of device was noted. It was the time from the end

of the propofol bolus to the connection of the airway to the breathing circuit and square wave capnograph.

The airway sealing pressure was determined by manometer stabilization method. After closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min, the pressure manometer was observed on positive pressure ventilation and the point where equilibrium was achieved was taken as the sealing pressure.

If an effective airway was not achieved then manipulations were done in the form of increasing the depth of insertion, jaw thrust, or chin lift or changing the size of the device.

The device insertion was abandoned after three unsuccessful attempts. Then, patient was given muscle relaxant and trachea was intubated with endotracheal tube.

Anesthesia was maintained on oxygen, nitrous oxide and propofol infusion with spontaneous respiration.

At end of the procedure, all the patients were ventilated with 100% oxygen during emergence from anesthesia. The device was removed when the patient was able to open the mouth on command. The patient was inspected for any injury to lips, teeth or tongue and the device was inspected for the presence of any blood stains. The mask of the supraglottic device was inspected for the presence of any gastric contents to confirm regurgitation. All the patients were observed for a period of 24 h for any complaints of sore throat. Sore throat in the postoperative period was treated using warm saline nebulization and in patients with sore throat 24 h later warm saline gargles were advised. Laryngospasm was given standard treatment. We gave 100% oxygen followed by injection scoline 0.5 mg/kg. Hiccups were tackled by increasing the depth of anesthesia by increasing the maintenance dose of Injection propofol.

Statistical analysis

Sample size was calculated based on the results of previous study^[5] to detect a projected difference in airway sealing pressure of 30% between groups with 80% power and 5% alpha error and a reported difference^[5] in airway sealing pressure of 15% between two groups, a sample size 22 patients were required, which was rounded off to 30 patients in each group.

The two groups were compared with each other in terms of age, weight, and sex. The statistical test used was Unpaired Student's *t*-test for age and weight. For qualitative data like the sex of the patient the statistical test employed was Chi-square test.

Hemodynamic parameters such as mean heart rate, BP both systolic and diastolic, respiratory rate, SpO₂ and end tidal CO₂ were compared using analysis of variance.

The mean time required for insertion and the mean seal pressure was compared using unpaired Student's *t*-test. The ease of insertion, attempts required for insertion, airway manipulations and the incidence of adverse events were compared using Chi-square test. In all the parameters, *P* < 0.05 was considered to be significant.

Results

The demographic profile was comparable among both groups [Table 1].

In both groups, the mean heart rate [Figure 1], other hemodynamic parameters and end-tidal CO₂ [Figure 2] were comparable.

Higher airway sealing pressure was noted with Group P (25.73 ± 02.21) as compared to Group I (20.07 ± 02.94) and the difference was statistically significant (*P* < 0.0001*). I-gel was faster and easier to insert than LMA-Proseal and this difference was statistically significant [Table 2].

Statistically, insignificant number of adverse effects were observed in 30% of the total cases from both groups. Out of these most common was sore throat and leak followed by coughing, laryngospasm and hiccups. There was no evidence of injury, regurgitation, aspiration, blood on device, and gastric insufflation [Table 3].

Discussion

Insertion of I-gel was easier and faster as compared to LMA-Proseal. LMA-Proseal is a complex device requiring an

Table 1: Demographic data

Parameter	Group I	Group P
Age*	30.83±9.83	33.77±9.47
Weight*	47.77±7.05	49.07±3.38
Sex (male:female)†	9:21	15:15
Type of surgery		
General surgery	21	22
Orthopedic	6	5
Plastic surgery	3	3

*Student's *t*-test, †Chi-square

Table 2: Comparison of airway sealing pressure, ease of insertion and insertion attempts

Parameters	Group I	Group P	P value
Airway sealing pressure	20.07±02.94	25.73±02.21	<i>P</i> < 0.0001*
Mean insertion time	29.53±08.23	41.00±09.41	0.000*
Ease of insertion			
Yes	29	24	<i>P</i> < 0.05*
No	1	6	
Insertion attempts			
1	29	24	<i>P</i> < 0.05*
2	1	6	

Table 3: Profile of adverse events

Events	Group I (N = 30) no. (%)	Group P (N = 30) no. (%)	P value
Coughing	03 (10.0)	—	0.075
Laryngospasm	—	02 (06.7)	0.150
Leak	04 (13.3)	02 (06.7)	0.389
Regurgitation	—	—	—
Injury	—	—	—
Sore throat	01 (03.3)	05 (16.7)	0.0852
Aspiration	—	—	—
Blood on device	—	—	—
Gastric insufflation	—	—	—
Hiccups	01 (03.3)	—	0.313
No. of patients	09 (30.0)	09 (30.0)	

By Chi-square test, *P* > 0.05 not significant

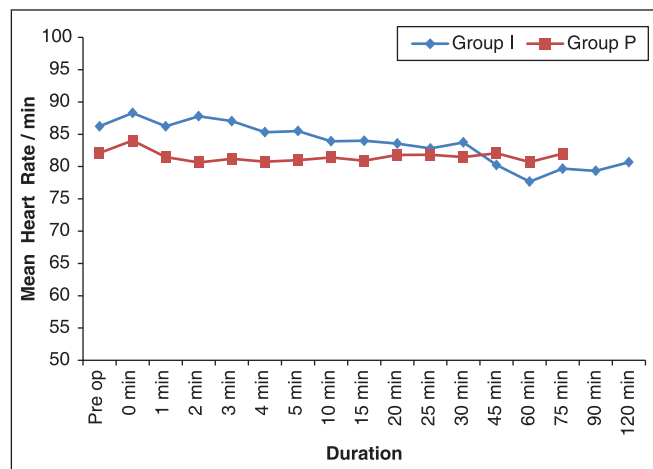


Figure 1: Comparison of changes in mean heart rate between two groups

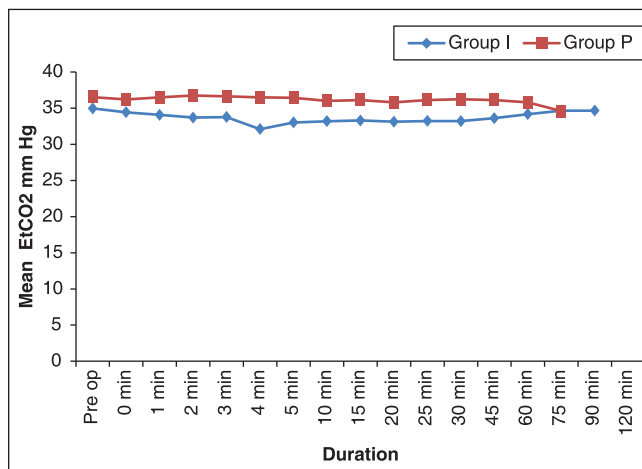


Figure 2: Comparison of changes in mean EtCO₂ between two groups

introducer for insertion, while an I-gel can be inserted without an introducer. As no cuff inflation is required in the I-gel, shorter time was required to achieve an effective airway by many investigators.^[5,6]

In 29/30 cases, I-gel was successfully inserted in first attempt, only once second attempt was required, whereas in LMA-Proseal first attempt was successful in 24/30 cases and six cases required a second attempt. The difference was clinically as well as statistically significant [Table 2]. There are many studies comparing LMA-Proseal with Classic LMA, in which they have observed lower first attempt insertion success with LMA-Proseal.^[7-9] The common reason which was stated was that when deflated, the semi-rigid distal end of the drain tube formed the leading edge of the LMA-Proseal, which was more rigid as compared to the softer I-gel. This factor could contribute to the difficult insertion of LMA-Proseal.^[8]

Levitan and Kinkle presumed that on insertion of LMA with inflatable mask the deflated leading edge of the mask can catch the edge of the epiglottis and cause it to downfold or impede proper placement beneath the tongue.^[10] Brimacombe *et al.* presumed that the difficulty in inserting the LMA-Proseal was caused by larger cuff impeding digital intra-oral positioning and propulsion into the pharynx, the lack of backplate making cuff more likely to fold over at the back of the mouth.^[9,11]

Airway manipulations were required in both groups to achieve an effective airway. The commonest manipulation required to achieve effective airway in Group I was increasing the depth of insertion ([5/30], 13.3%), whereas in the Group P, the device had to be changed ([6/30], 20%). The overall requirement of manipulations was less in the Group I ([8/30], 26.66%) as compared to Group P ([13/30], 43.33%) [Figure 3]. Kannaujia *et al.* also reported similar findings with respect to I-gel.^[6]

The mean airway sealing pressure with I-gel was 20.07 ± 0.294 cm H₂O, and with LMA-Proseal 25.73 ± 0.221 cm of H₂O which was statistically significant ($P = 0.0000^*$) [Table 2], but it was not clinically significant. The higher values of EtCO₂ among the LMA-Proseal group can explain the high airway sealing pressure and a better seal provided by it. Though the seal pressure of I-gel was lower than that of LMA-Proseal, it was enough to provide optimum ventilation.

Gabbott *et al.* also concluded that I-gel provides a good airway sealing pressure which improved over time and may be due to the thermoplastic properties of gel cuff which forms an effective seal around the larynx after warming to body temperature.^[12] Various studies have been conducted comparing the seal

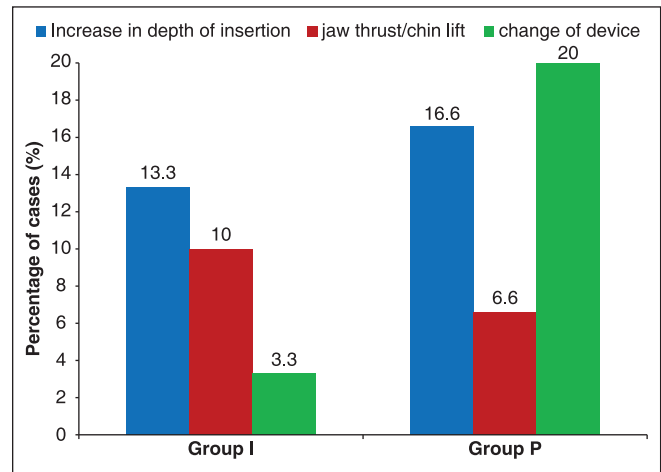


Figure 3: Profile of airway manipulations required

pressures of I-gel with other LMA's, which conclude that an I-gel has an airway sealing pressure almost similar to the LMA-Proseal and more than the Classic LMA and LMA-Unique, hence can be used for positive pressure ventilation without the risk of aspiration.^[13-15]

We compared the incidence of adverse effects intraoperatively, during emergence and in the postoperative period. Intraoperatively leak was present in 4/30 (13.3%) cases of the I-gel and 2/30 (6.7%) cases with the LMA-Proseal. The leak was diagnosed by the audible noise during assisted ventilation. The lower incidence of leak with the LMA-Proseal can be attributed to the higher airway sealing pressure. Though there was leak, good oxygenation and ventilation was maintained with both devices. Our results were in concordance with those found by Gasteiger *et al.*^[16]

There was no evidence of regurgitation and aspiration with either of the devices. In our study, we included only elective patients who were adequately fasting preoperatively and all the patients had nasogastric tube *in situ* so none of the patients had episode of regurgitation. There was no evidence of injury to lip, teeth or tongue, and blood on either device.

There was no incidence of gastric insufflation with either device probably due to a good seal of ventilation around the laryngeal inlet and presence of nasogastric tube through the gastric channel. Brimacombe *et al.*^[17] described one case of gastric insufflation with LMA-Proseal, wherein the tip of the LMA-Proseal had folded posteriorly after insertion resulting in the failure of the drainage tube to perform its intended function.

In the I-gel group, 3.3% cases complained of sore throat immediately in the postoperative period whereas in the LMA-Proseal group 16.7% patients complained of sore throat. 24 h

later the same patient had sore throat in I-gel group where as in the LMA-Proseal group 23.3% patients complained of throat discomfort. The difference was statistically significant ($P < 0.05^*$). Soliveres *et al.* also found that the use of LMA-Proseal produces more sore throat as compared to the I-gel.^[18] Various studies have reported similar findings wherein the incidence of sore throat is minimal with I-gel in comparison with other supraglottic airway devices.^[5,14,19,20] The lower incidence of sore throat in our study can be attributed to the soft seal non inflatable mask of I-gel. I-gel being a supraglottic airway device without an inflatable mask has some potential advantage of easier insertion and minimal tissue compression^[21-23] whereas supraglottic airway device with inflatable cuff like the LMA-Proseal in our study can absorb anesthetic gases leading to increased mucosal pressure.^[24]

Conclusion

I-gel is a simple device which is easy to insert without much of manipulations rapidly. It has a potential advantage of effective seal pressure which is less as compared to LMA-Proseal, but is enough to prevent aspiration and maintain an effective ventilation and oxygenation. Lack of inflatable cuff also resulted in lower incidence of sore throat. Thus an I-gel can be a useful tool for maintaining airway and intermittent positive pressure ventilation.

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